

Public Case Detail

Cases Count: 393

Case Number : 231515

Data Entry Date : 03/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/03/1974

Outcome :

Causality : Causality possible

Unknown

Information: White blood cell count and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	

Medicine details :

CLOPINE (Suspected)	Reason :	
Tablet	200 Milligram	Daily
		Oral
Batch :	Started : 05/06/2007	Stopped : 27/06/2007

Public Case Detail

Cases Count: 393

Case Number : 231531

Data Entry Date : 06/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 28/06/2007

Age :

DOB : 31/10/1961

Outcome :

Causality : Causality possible

Not yet recovered

Information: White blood cell (WBC) and neutrophil counts (NC) had been normal for the treatment period prior to this event.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia and leucopenia.	Ceased clopine.
Leukopenia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily Oral
Batch :	Started : 17/11/2003 Stopped : 29/06/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		31/05/2007	11.30	
White blood cells		25/06/2007	3.60	
White blood cells		28/06/2007	2.70	
White blood cells		30/06/2007	4.50	
White blood cells		05/07/2008	7.60	
Neutrophils		31/05/2007	5.70	
Neutrophils		25/06/2007	1.80	
Neutrophils		28/06/2007	0.80	
Neutrophils		30/06/2007	1.80	
Neutrophils		05/07/2008	5.30	

Case Number : 231546

Data Entry Date : 06/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/07/1975

Outcome :

Causality : Causality probable

Unknown

Information: Patient commenced treatment with clozapine on 2/08/2004 for treatment of schizophrenia and switched to Clopine (clozapine) on 7/11/2006. Patient has been taking Clopine PO 900mg daily since commencing Clopine treatment.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased		Patient experienced reduced left ventricular function, chest pain, shortness of breath, sinus tachycardia, supraventricular ectopic beats, elevated creatine kinase and elevated triglycerides whilst on Clopine.	Clopine treatment is continuing pending advice from cardiologist.
Blood creatine phosphokinase increased			
Blood triglycerides increased			
Chest pain			
Dyspnoea			
Sinus tachycardia			
Supraventricular extrasystoles			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	900 Milligram	Daily	Oral
Batch :	Started : 07/11/2006	Stopped : 09/08/2007	Contin

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				ECHO was normal pre-clozapine commencement (with the exception of sinus tachycardia. 12/08/2004 ECHO sinus tachycardia (130BPM). 30/04/2007 ECHO sinus tachycardia 900mg 30/04/2007 ECHO ejection fraction 46% 900mg
Creatine phosphokinase		18/06/2007	290	
Triglyceride		18/06/2007	6.5	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				18/01/2006 ECG Supraventricular ectopic 700mg.

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Cases Count: 393

Case Number : 231547

Data Entry Date : 06/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/06/2007

Age :

Outcome : 02/07/2007

DOB : 22/09/1971

Recovered

Causality : Causality probable

Information: The patient commenced treatment with Clopine on 6/06/2007 and was titrated up to po 225mg daily. In June 2007, the patient experienced the event.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis. Tachycardia (140), Hypotension (100/60) and elevated creatine kinase (67) and troponin 1 increased (0.45)	Clopine ceased.
Pyrexia		Temp of 38.5 degrees C	
Blood creatine phosphokinase increased			
Hypotension			
Tachycardia			
Troponin I increased			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily Oral
Batch :	Started : 06/06/2007 Stopped : 21/06/2007 0
SODIUM VALPROATE (Other drug)	Reason :
	1.4 Gram
Batch :	Started : Stopped :
VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason : Depression
	150 Milligram Daily
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				White cell counts were within the normal range throughout treatment.
Neutrophils				Neutrophil counts were within the normal ranges throughout treatment.

Case Number : 231548

Data Entry Date : 06/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 60.5

Onset Date : 22/06/2007

Age :

DOB : 02/05/1979

Outcome : 27/06/2007

Causality : Causality possible

Recovered

Information: Positive dechallenge.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experienced severe tachycardia, moderate fever, headache, myalgia.	Clopine discontinued.
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 12/06/2007	Stopped : 23/06/2007	
SODIUM VALPROATE (Other drug)		Reason :	
	1 Gram		
Batch :	Started : 12/04/2007	Stopped :	
ZUCLOPENTHIXOL DECANOATE (Other drug)		Reason :	
Injection	200 Milligram		Intramuscular
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				22/06/2007 Cardiac rate 136bpm. 23/06/2007 Cardiac rate 144 bpm.
Blood pressure		22/06/2007	120/80	
Blood pressure		23/06/2007	110/60	
Temperature		22/06/2007	38	
Temperature		23/06/2007	38	

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Case Number : 231549

Data Entry Date : 06/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/06/2007

Age :

DOB : 08/11/1953

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced neuroleptic malignant syndrome whilst on Clozaril treatment.	Clozaril put on hold.

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 13/06/2007	Stopped :	

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Cases Count: 393

Case Number : 231573

Data Entry Date : 07/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 29/10/1969

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient experienced myocarditis	ceased treatment

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 18/06/2007	Stopped :	02/07/2007

Case Number : 231577

Data Entry Date : 07/08/2007

Gender : F

Hospitalisation : Required a specialist consultation

Weight (kg) : 0

Onset Date : 03/07/2007

Age :

DOB : 25/09/1943

Outcome :

Causality : Causality possible

Not yet recovered

Information: Patient had experienced seizures in 1998-1999. Dose of Clozaril had been reduced and valproate dose increased.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced seizures.	Clozaril ceased and recommenced at a lower dose of 200mg/daily form 350mg/daily.
Drug level below therapeutic	Caused or prolonged inpatient hospitalisation		
Leukopenia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 23/11/2001	L TERM	Stopped : 19/09/2007 0
SODIUM VALPROATE (Other drug)		Reason :	
Batch :	Started :	Stopped :	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		31/12/2006	136	Low valproate levels
Serum drug level		22/03/2007	342	Low valproate levels
Serum drug level		26/04/2007	284	Low valproate levels
White blood cells		17/09/2007	3.30	
White blood cells		19/09/2007	2.70	
White blood cells		20/09/2007	3.20	
White blood cells		21/09/2007	3.20	
White blood cells		24/09/2007	4.30	
White blood cells		25/09/2007	3.40	
White blood cells		28/09/2007	3.70	
White blood cells		01/10/2007	3.30	

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Case Number : 231626

Data Entry Date : 08/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2007

Age :

Outcome :

DOB : 11/08/1971

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	ceased treatment with Clopine
Pyrexia			

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 21/06/2007	Stopped : 04/07/2007	0
GLICLAZIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
METFORMIN HYDROCHLORIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin				Troponin I increased
Creatine phosphokinase				Creatine kinase increased

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Case Number : 231628

Data Entry Date : 08/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/12/1966

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction		Ventricular dysfunction	Clozaril was ceased

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 29/01/2001	Stopped :	03/07/2007

Public Case Detail

Cases Count: 393

Case Number : 231691

Data Entry Date : 08/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/06/2007

Age :

DOB : 28/05/1967

Outcome : 13/06/2007

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction		Patient experienced a bowel obstruction.	Temporary discontinuation of Clozaril

Medicine details :			
CLOZARIL (Suspected)		Reason : Schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 07/11/1997	Stopped : 12/06/2007	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Abdomen X-ray				Abdominal x-ray 6/6/07: Early or partial small bowel obstruction in meddle small bowel.

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Case Number : 231695

Data Entry Date : 09/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2007

Age :

DOB : 17/01/1933

Outcome :

Causality : Causality certain

Not yet recovered

Information: Rechallenged with Clozaril 300mg daily with subsequent drop in conscious state. That patient also had a history of alcohol abuse. PMHx Diabetes mellitus, Transient ischaemic attack and Cerebrovascular accident.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dysarthria	Caused or prolonged inpatient hospitalisation	Patient was hospitalised after a physical decline in function for three weeks, increasing difficulty to walk, speech increasingly incomprehensible and difficulty in swallowing, 2 weeks of jerky limb movements. The patient was drowsy and incontinent, a diagnosis of seizures secondary to clozapine/lithium toxicity was made.	Lithium ceased, clozaril temporarily ceased, rechallenged, dosage reduced to 150mg daily. Commenced valproate.
Convulsion	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Dysphagia	Caused or prolonged inpatient hospitalisation		
Incontinence	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 300 Milligram Daily Oral

Batch : Started : 17/02/2000 Stopped : 30/05/2007 0

LITHIUM CARBONATE (Other drug)

Reason :

375 Milligram Alternate days

Batch : Started : Stopped : 30/05/2007 0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				30 May 2007: Clozapine level = 435, Lithium level = 0.84 (0.60-1.00). Estimated Glomerular Filtration Rate (GFR): 42 mL/min/173m2.
Sodium		30/05/2007	156	
Creatinine		30/05/2007	116	
Electroencephalograph				1 June 2007: EEG showed frontotemporal epileptiform activity (left>right).

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Case Number : 231706

Data Entry Date : 09/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/07/2007

Age :

DOB : 05/02/1977

Outcome : 01/07/2007

Causality : Causality possible

Death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Death Unexplained	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 25/01/2007	Stopped : 01/07/2007	

Public Case Detail

Cases Count: 393

Case Number : 231739

Data Entry Date : 09/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 130

Onset Date : 02/03/2007

Age :

DOB : 07/08/2007

Outcome :

Causality : Causality possible

Not yet recovered

Information: Smoker 15 cig/day.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased	Life threatening	On commencement of Clozapine therapy echo showed left ventricular ejection decreased (from Echo in May 2005) . Other side effects included hypersalivation and increased urinary micturition, as well as weight gain. Grade b heart failure.	Initiation of Beta Blocker ACE-I therapy
Cardiac failure	Life threatening		
Polyuria	Life threatening		
Salivary hypersecretion	Life threatening		
Weight increased	Life threatening		

Medicine details :

CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet

700 Milligram

Daily

Oral

Batch :

Started :

Stopped : 28/03/2007

Case Number : 231798

Data Entry Date : 10/08/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 78

Onset Date : 06/07/2007

Age :

DOB : 26/02/1973

Outcome :

Causality : Causality possible

Not yet recovered

Information: Half brother has IDDM

Reaction :

Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis	Life threatening	Patient experienced diabetic ketoacidosis - flu-like symptoms, abdominal pains, productive cough, shortness of breath, pale, lethargic, confusion.	
Abdominal pain	Life threatening		
Confusional state	Life threatening		
Dyspnoea	Life threatening		
Influenza like illness	Life threatening		
Lethargy	Life threatening		
Pallor	Life threatening		
Productive cough	Life threatening		

Medicine details :

CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet

250 Milligram

Daily

Oral

Batch :

Started :

L TERM

Stopped : 11/07/2007

Public Case Detail

Cases Count: 393

Case Number : 231833

Data Entry Date : 10/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/06/1937

Outcome :

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 14/02/2007	Stopped : 31/07/2007	

Public Case Detail

Cases Count: 393

Case Number : 231847

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/05/2007

Age :

DOB : 16/04/1973

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Epilepsy		Patient was commenced on Clozaril on 24 Feb 2005. In June 2007 the patient complained of blackouts. An EEG was performed and showed clear epileptic features.	Patient commenced antiepileptic Epilim (sodium valproate). Clozaril dose was slowly reduced.
Electroencephalogram abnormal			
Loss of consciousness			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 24/02/2005	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Electroencephalograph				EEG showed clear epileptic features.

Public Case Detail

Cases Count: 393

Case Number : 231849

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/07/2007

Age :

DOB : 06/12/1952

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Patient was taking Clozaril since 19 Nov 1998. On 8 July 2007 the patient collapsed and was hospitalised. Clozaril treatment remained ongoing.	Aspirin and Citalopram
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation		
Drug level increased	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 19/11/1998	Stopped :	
CIPRAMIL (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin	<0.08	12/12/2006	0.01	
Troponin	<0.08	08/07/2007	0.16	
Troponin	<0.08	12/07/2007	0.04	
Serum drug level	350 - 450	21/08/2007	692	Clozapine levels in 2002 were 254.

Public Case Detail

Cases Count: 393

Case Number : 231852

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 06/07/2007

Age :

DOB : 21/08/1985

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient was taking Clozril since 15 June 2007. On 6 July 2007 the patient was diagnosed with myocarditis.	Ceased Clozaril
Blood creatine phosphokinase increased			
Pyrexia			
Tachycardia			
Troponin I increased			

Medicine details :

CLOZARIL (Suspected)	Reason : Othr&unspec metabolic diseases		
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 15/06/2007	Stopped : 06/07/2007	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		05/07/2007	70	
Creatine phosphokinase		09/07/2007	81	
Creatine phosphokinase		13/07/2007	90	
Troponin		05/07/2007	0.15	
Troponin		09/07/2007	0.25	
Troponin		13/07/2007	<0.10	

Case Number : 231854

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/06/2007

Age :

DOB : 31/05/1970

Outcome :

Causality : Causality possible

Unknown

Information: The patient had normal Troponin results.
It was not confirmed if Clozaril was ceased.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction		Patient was on Clozaril morning and evening. Patient had regular Doppler echocardiography which showed deterioration of left and right ventricular function. Creatine Kinase increased (CK 501). Patient consulted a cardiologist who suggested Clozaril should be ceased. It was not confirmed if Clozaril was ceased. Olanzapine and Valproate was commenced.	
Blood creatine phosphokinase increased			

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 22/06/1999	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		28/06/2007	501	
Creatine phosphokinase		04/07/2007	189	
Creatine phosphokinase		07/07/2007	228	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				<p>09 Dec 2005 Doppler echocardiography: 1. Normal left ventricular size and function 2. No significant valvular abnormalities.</p> <p>28 Dec 2005 Doppler Exhocardiography: 1. Normal left ventricular cavity size and borderline normal systolic function 2. No significant valvular abnormalities.</p> <p>12 Jun 2007 Doppler Echocardiography: Normal left ventricular size with mildly impaired systolic function. 2. Upper normal right ventricular dimensions with mildly impaired systolic function. 3. No significant valvular abnormalities 4. Some deterioration of left and right ventricular function.</p>

Public Case Detail

Cases Count: 393

Case Number : 231863

Data Entry Date : 13/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 02/07/2007

Age :

Outcome :

DOB : 30/09/1941

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Left ventricular failure	Caused or prolonged inpatient hospitalisation	Non-specific intraventricular conduction block. Left ventricular failure.	

Medicine details :			
CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	300 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
Aripiprazole (Other drug)		Reason :	
Batch :	Started :	Stopped :	
ATORVASTATIN (Other drug)		Reason :	
Batch :	Started :	Stopped :	
Bisoprolol Fumarate (Other drug)		Reason :	
Batch :	Started :	Stopped :	
FRUSEMIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
TRANDOLAPRIL (Other drug)		Reason :	
Batch :	Started :	Stopped :	
VENTOLIN (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Case Number : 231866

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 24/06/2007

Age :

DOB : 26/11/1981

Outcome :

Causality : Causality possible

Not yet recovered

Information: History of Alcoholism and Renal impairment. The physician stated that the high urea and high creatinine were also pre-existing conditions. Recovered from the increased c-reactive protein and increased blood glucose.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient experienced pyrexia, c-reactive protein increased, blood creatinine increased and blood glucose increased.	
Abdominal pain			
Blood creatinine increased			
Blood glucose increased			
C-reactive protein increased			
Cough			
Malaise			
Nasal congestion			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	200 Milligram Daily Oral
Batch :	Started : 22/06/2007 Stopped : Ongoing.
LIPITOR (Other drug)	Reason :
Batch :	Started : Stopped :
LORAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
THIAMINE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatinine	<10			CRP: 229, 252, 43 and on 17 July CPR: 4.
Serum glucose	3.8 - 5.5	02/07/2007	8.8	
Serum glucose	3.8 - 5.5	10/07/2007	5	

Public Case Detail

Cases Count: 393

Case Number : 231877

Data Entry Date : 13/08/2007
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 13/03/1948
Causality : Causality possible

Information: Patient has had a previous history of bowel obstruction.

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Patient had bowel obstruction whilst on Clopine therapy.	Required surgical intervention. Clopine ceased for 3 days, but is not continuing.

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 18/05/2006	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 231894

Data Entry Date : 13/08/2007

Gender : F

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date : 30/06/2007

Age :

Outcome : 03/07/2007

DOB : 11/12/1982

Recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	On the night of 01/07/07, patient overdosed on Clopine by taking 1050mg oral instead of 200mg oral and experienced drowsiness and chest tightness.	Taken to emergency department for monitoring.
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	1 Gram	1 time	Oral
Batch :	Started : 30/06/2007	Stopped :	0

Case Number : 231940

Data Entry Date : 14/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 02/07/2007

Age : 37Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis. Creatine kinase increased.	Cessation of Clozapine. Commenced aspirin, bisoprolol and paracetamol
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 18/06/2007	Stopped : 02/07/2007	
SOMAC (Other drug)		Reason :	
Tablet	40 Milligram		Oral
Batch :	Started : 12/06/2007	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				LVEF 312
Creatine phosphokinase		02/07/2007	463	
Creatine phosphokinase		03/07/2007	290	
Troponin		02/07/2007	3.06	
Troponin		03/07/2007	2.99	
C-Reactive Protein		02/07/2007	265.7	

Public Case Detail

Cases Count: 393

Case Number : 231943

Data Entry Date : 14/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 04/01/1975

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis/pericarditis	
Pericarditis	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason :
Tablet	75 Milligram Daily Oral
Batch :	Started : 05/07/2007 Stopped :

Case Number : 232018

Data Entry Date : 15/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/05/2007

Age :

DOB : 24/06/1967

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiac enzymes increased		Raised cardiac enzymes. Shortness of breath. Central chest tightness.	Clozaril ceased
Blood creatine phosphokinase increased			
Chest discomfort			
Dyspnoea			
Monocyte count increased			
Treatment noncompliance			
Troponin I increased			

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 25/11/2005	Stopped : 03/02/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		05/07/2007	328	
Creatine phosphokinase		16/07/2007	108	
Troponin		05/07/2007	0.05	
Troponin		16/07/2007	0.03	
Monocytes	(02.8)	21/05/2007	0.9	
Monocytes	(02.8)	16/07/2007	0.8	
Electrocardiography				No acute changes.
Other data				12 Jul 2007 Transthoracic echocardiogram:normal.

Public Case Detail

Cases Count: 393

Case Number : 232059

Data Entry Date : 16/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/07/2007

Age :

DOB : 25/09/1974

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutrophilia		Patient experienced neutrophilia. Leukocytosis.	
Leukocytosis			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	150 Milligram	Daily	Oral
Batch :	Started : 22/08/2006	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		09/07/2007	32.6	
Neutrophils		09/07/2007	27.10	



Public Case Detail

Cases Count: 393

Case Number : 232060

Data Entry Date : 16/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 29Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain. Troponin I increased. Blood creatine phosphokinase increased. Blood creatine phosphokinase MB increased.	
Blood creatine phosphokinase MB increased			
Blood creatine phosphokinase increased			
Troponin I increased			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232099

Data Entry Date : 16/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/04/2007

Age :

Outcome : 12/04/2007

DOB : 14/10/1980

Recovered

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Tachycardia	Incapacity/disability	Patient experienced tachycardia. Unresponsive to beta-blockers and worsened by anxiety.	Patient ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	650 Milligram	Daily	Oral
Batch :	Started : 13/09/2004	Stopped : 11/04/2007	

Public Case Detail

Cases Count: 393

Case Number : 232149

Data Entry Date : 17/08/2007

Hospitalisation :

Onset Date : 15/07/2007

Outcome :
Unknown

Gender : F

Weight (kg) : 0

Age :

DOB : 04/01/1975

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced Myocarditis in July after treatment with Clopine.	Ceased treatment.

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 05/07/2007	Stopped : 23/07/2007	

Public Case Detail

Cases Count: 393

Case Number : 232150

Data Entry Date : 17/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 14/10/1977

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased treatment

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 28/06/2007	Stopped : 23/07/2007	

Case Number : 232152

Data Entry Date : 17/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/05/2007

Age :

DOB : 21/07/1970

Outcome :

Causality : Causality possible

Recovered

Information: History of epilepsy and fits.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pleural effusion	Caused or prolonged inpatient hospitalisation	Eosinophilic pleural effusion, eosinophilia and neutropenia.	Clozaril discontinued. Treated with antibiotics and received an aspiration of the effusion.
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	200 Milligram Daily Oral
Batch :	Started : 04/05/2007 Stopped : 29/05/2007
LAMICTAL (Other drug)	Reason :
Batch :	Started : Stopped :
QUETIAPINE (Other drug)	Reason :
Batch :	Started : Stopped :
SODIUM VALPROATE (Other drug)	Reason :
Batch :	Started : Stopped :
VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 232178

Data Entry Date : 17/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2007

Age :

DOB : 09/05/1961

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Depressed mood		Patient experienced nausea, some lethargy and depressed mood.	
Lethargy			
Nausea			

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 25/03/1996	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232230

Data Entry Date : 20/08/2007

Hospitalisation :

Onset Date : 26/06/2007

Outcome : 26/06/2007

Death

Gender : F

Weight (kg) : 0

Age :

DOB : 20/02/1976

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Sudden death	Death	Patient experienced sudden death.	

Medicine details :			
CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 26/05/1997	Stopped : 26/06/2007	
DIAZEPAM (Other drug)	Reason :		
Batch :	Started :	Stopped :	
DIAZEPAM (Other drug)	Reason :		
Batch :	Started :	Stopped :	
SODIUM VALPROATE (Other drug)	Reason :		
Batch :	Started :	Stopped :	
SODIUM VALPROATE (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232258

Data Entry Date : 20/08/2007
Hospitalisation : Admitted to hospital
Onset Date : 22/07/2007
Outcome :
 Unknown

Gender : F
Weight (kg) : 0
Age :
DOB : 25/02/1942
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a seizure, lower respiratory tract infection and pyrexia.	
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 22/08/1996	L TERM	Stopped : Ongoing.

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		04/06/2007	15.9 x 10 ⁹ /L	
White blood cells		29/06/2007	12.3 x 10 ⁹ /L	
Neutrophils		04/06/2007	12.0 x 10 ⁹ /L	
Neutrophils		29/06/2007	12.30 x 10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 232272

Data Entry Date : 20/08/2007
Hospitalisation : Admitted to hospital
Onset Date : 02/06/2007
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 19/01/1980
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experienced tachycardia, raised blood creatine, troponin increased, flu like symptoms, myalgia and fever.	
Blood creatine increased	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZAPINE (Suspected)	Reason : Other myocardial insufficiency		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 16/05/2007	Stopped : 03/06/2007	0

Public Case Detail

Cases Count: 393

Case Number : 232306

Data Entry Date : 21/08/2007
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 08/08/1978
Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Urinary incontinence	Caused or prolonged inpatient hospitalisation	Urinary incontinence (nocturnal). Patient has been tried on Oxybutynin and Desmopressin nasal spray without much effect. Patient attempted suicide as she felt she was disgusting upon recurrence of incontinence. Threatens to suicide if maintained on Clozapine.	Oxybutynin and Desmopressin. Cessation of Clozapine.

Medicine details :			
CLOZAPINE (Suspected)			
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 06/12/2006	Stopped : 01/08/2007	
Ciclesonide (Other drug)			
Inhalation	80 Microgram		Oral
Batch :	Started :	Stopped :	
OMEPRAZOLE (Other drug)			
Batch :	Started :	Stopped :	
SALBUTAMOL (Other drug)			
Batch :	Started :		Inhalation
		Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232364

Data Entry Date : 22/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 43Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: the reporting healthcare practitioner suspected that the event may be due to lithium overdose but was unsure.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Renal failure acute		Patient experienced acute renal failure.	

Medicine details :

CLOZAPINE (Suspected)		Reason :	
Tablet	200 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
LITHIUM CARBONATE (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232432

Data Entry Date : 23/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 16/12/1986

Outcome :

Causality : Causality possible

Unknown

Information: white blood cell counts and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures while being treated with Clopine.	Ceased treatment

Medicine details :

CLOZAPINE (Suspected)		Reason :	
Tablet	650 Milligram	Daily	Oral
Batch :	Started : 13/11/2006	Stopped :	0

Public Case Detail

Cases Count: 393

Case Number : 232440

Data Entry Date : 23/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 07/09/1977

Outcome :

Causality : Causality possible

Unknown

Information: WCC and NC have been within the normal ranges throughout treatment.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures while being treated with Clopine.	dose reduction from 700mg to 650mg

Medicine details :

CLOZAPINE (Suspected)		Reason :	
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 11/01/2005	Stopped :	0

Case Number : 232463

Data Entry Date : 24/08/2007

Hospitalisation :

Onset Date : 05/08/2007

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age :

DOB : 21/07/1986

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis, cardiomyopathy and neutropenia while being treated with Clozaril..	Ceased treatment.
Cardiomyopathy			
Neutropenia			

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 30/06/2007	Stopped :	05/08/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		05/08/2007	0.90 x 10 ⁹ /L	
Neutrophils		06/08/2007	1.1 x 10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 232506

Data Entry Date : 27/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/06/2007

Age :

DOB : 15/04/1966

Outcome :

Causality : Causality probable

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased	Death	Patient experienced a red range blood count and neutrophil count decreased.	Clozaril ceased.
Neutrophil count decreased	Death		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 11/12/2006	Stopped : 27/06/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		26/06/2007	3.80 x 10 ⁹ /L	
Neutrophils		26/06/2007	1.40 x 10 ⁹ /L	

Case Number : 232507

Data Entry Date : 27/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 58.5

Onset Date : 12/07/2007

Age :

DOB : 21/08/1978

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular hypertrophy		Patient experienced mild septal hypertrophy, mild QTc prolongation and sinus tachycardia whilst on Clopin therapy.	
Electrocardiogram QT prolonged			
Sinus tachycardia			

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet 700 Milligram Daily Oral

Batch : Started : 02/05/2006 Stopped :

CHLORPROMAZINE HYDROCHLORIDE (Other drug)

Reason :

Batch : Started : Stopped :

ZOPICLONE (Other drug)

Reason :

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		12/07/2007	Mild septal hypertrophy	Patient reported to be asymptomatic.
Echocardiogram		12/07/2007	Sinus tachycardia (115-120bpm)	Patient reported to be asymptomatic.
Echocardiogram		27/07/2007	Mild QTc prolongation (452)	Patient reported to be asymptomatic.

Public Case Detail

Cases Count: 393

Case Number : 232511

Data Entry Date : 27/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 21/10/1939

Outcome :

Causality : Causality possible

Unknown

Information: White blood cell count and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Whilst on Clopine therapy, patient developed myocarditis.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

175 Milligram

Daily

Oral

Batch :

Started : 30/08/2005

Stopped : 10/07/2007

Public Case Detail

Cases Count: 393

Case Number : 232530

Data Entry Date : 27/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/07/2007

Age :

Outcome : 26/07/2007

DOB : 10/11/1968

Death

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient commenced treatment with Clopine on 22/05/06 and was titrated to a maximum dose of 600mg daily, which the patient was taking at the time of death. Cause of death was unknown at the time of reporting.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 22/05/2006	Stopped : 26/07/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				White blood cell count and neutrophil counts were within normal ranges for the treatment period, with exception of a few slightly raised counts on two testing occasions.

Public Case Detail

Cases Count: 393

Case Number : 232611

Data Entry Date : 28/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 27/01/1974

Outcome :

Causality : Causality possible

Unknown

Information: White blood cell counts and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 24/07/2007	Stopped : 07/08/2007	

Case Number : 232613

Data Entry Date : 28/08/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 15/07/2007

Age :

DOB : 10/05/1954

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Patient experienced a bowel obstruction and white blood cell counts and neutrophil counts were high on several test occasions throughout the duration of treatment, and the patient had also experienced neutropenia in 2004.	Patient required surgery.
Neutropenia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	700 Milligram Daily Oral
Batch :	Started : 02/10/2002 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		28/05/2007	17.80 x10 ⁹ /L	700mg
Neutrophils		28/05/2007	15.00 x10 ⁹ /L	700mg

Public Case Detail

Cases Count: 393

Case Number : 232642

Data Entry Date : 28/08/2007

Gender : F

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 18/07/2007

Age :

DOB : 30/01/1977

Outcome : 18/07/2007

Causality : Causality possible

Unrelated death

Information: History of obesity.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Sudden death	Death	Patient died a sudden death.	

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 17/07/2007	Stopped : 18/07/2007	
SEROQUEL (Suspected)		Reason :	
Tablet			Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232660

Data Entry Date : 29/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 24/08/1961

Outcome :

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	475 Milligram	Daily	Oral
Batch :	Started : 06/03/2004	Stopped : 27/07/2007	

Public Case Detail

Cases Count: 393

Case Number : 232723

Data Entry Date : 29/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/11/1984

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Heart rate increased		Patient experienced an increased heart rate of 145 beats per minute. White blood cell count decreased to 3.4. Neutrophil count decreased to 1.4.	Clozaril ceased.
Neutropenia			
White blood cell count decreased			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 24/09/2002	Stopped : 14/07/2004	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Heart Rate				145bpm
White blood cells		10/07/2004	3.9	
White blood cells		19/07/2004	3.4	
Neutrophils		16/07/2004	1.8	
Neutrophils		19/07/2004	1.4	

Public Case Detail

Cases Count: 393

Case Number : 232724

Data Entry Date : 29/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/02/1982

Outcome :

Causality : Causality possible

Unknown

Information: Laboratory tests of WBC and NC were within the normal range.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis while on Clozaril. WBC and NC were within the normal range.	Ceased Clozaril

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 17/07/2007	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 232731

Data Entry Date : 30/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 70

Onset Date : 15/07/2007

Age :

DOB : 31/08/1978

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular hypertrophy		Mild left ventricular hypertrophy with good left ventricular function on echo 12/07/07. Toxic clozapine level of 100 on 24/07/07, mild increase QTc of 452 and tachycardia.	Clozapine dose reduced from 700mg to 600mg.
Drug level above therapeutic			
Electrocardiogram QT prolonged			
Tachycardia			

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin				LD = normal troponin.
Other data				Heart rate = 112.

Case Number : 232732

Data Entry Date : 30/08/2007

Gender : M

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 74

Onset Date : 20/07/2007

Age :

Outcome : 24/07/2007

DOB : 14/10/1977

Recovered

Causality : Causality probable

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Suspected clozapine induced myocarditis, retrosternal chest pain, intermittent tachycardia, low grade temperature, mildly increased eosinophils, ESR increased and CRP increased.	Clozapine ceased.
C-reactive protein increased			
Chest pain			
Eosinophil count increased			
Pyrexia			
Red blood cell sedimentation rate increased			
Tachycardia			
Troponin increased			

Medicine details :

CLOZAPINE (Suspected)	Reason : Other myocardial insufficiency		
Tablet	425 Milligram	Daily	Oral
Batch :	Started : 28/06/2007	Stopped : 23/07/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin				Troponin peaked at 0.09 21/07/07.
Echocardiogram				Echo normal.

Public Case Detail

Cases Count: 393

Case Number : 232872

Data Entry Date : 31/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/07/1963

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Vomiting		Patient was on Clozaril since 9 Oct 2006. On 14 Aug 2007 the dosage was increased to 550 mg daily which caused the patient to be physically sick (vomiting). Patient ceased taking Clozaril.	Ceased Clozaril
Malaise			

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	550 Gram	Daily	Oral
Batch :	Started : 09/10/2006	Stopped : 20/08/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				normal
Neutrophils				normal

Public Case Detail

Cases Count: 393

Case Number : 232874

Data Entry Date : 31/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/07/1963

Outcome :

Causality : Causality probable

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient ceased taking Clozaril due to it making her sick. Patient experienced seizures. Patients white blood cell and neutrophils count were within the normal range.	

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
	550 Milligram	Daily	
Batch :	Started :	Stopped : 20/08/2007	0

Public Case Detail

Cases Count: 393

Case Number : 232887

Data Entry Date : 03/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/08/2007

Age :

DOB : 21/02/1957

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		Myocardial infarction. Patient commenced treatment with Clopine on 25/7/07 for the treatment of schizophrenia. On 8/8/07 patient experienced fever and elevated troponin level which were reported to be mild in intensity. Patient had a myocardial infarction at an unknown date in August 2007 and ceased treatment.	Ceased Clozapine.
Pyrexia			
Troponin increased			

Medicine details :			
CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 25/07/2007	Stopped : 09/08/2007	
Aripiprazole (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin				elevated
White blood cells				normal
Troponin		08/08/2007	increased 0.08	

Public Case Detail

Cases Count: 393

Case Number : 233069

Data Entry Date : 05/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/08/2007

Age :

DOB : 11/05/1983

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient commenced treatment with clozapine in April 02 and switched to Clopine in Jan 2007. In August 07 blood tests revealed neutropenia and leucopenia.	Ceased Clopine
Leukopenia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	600 Milligram Daily
Batch :	Started : 11/01/2007 Stopped : 22/08/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		26/07/2007	5.70	Dose/mg - 0.0/600.0
White blood cells		22/08/2007	2.70	Dose/mg - 0.0/600.0
Neutrophils		26/07/2007	2.80	Dose/mg - 0.0/600.0
Neutrophils		22/08/2007	0.63	Dose/mg - 0.0/600.0

Public Case Detail

Cases Count: 393

Case Number : 233108

Data Entry Date : 06/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 04/03/1963

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Breast cancer		Patient developed breast cancer.	Clopine ceased.

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	450 Milligram	Daily	Oral
Batch :	Started : 19/10/2004	Stopped :	16/07/2007

Public Case Detail

Cases Count: 393

Case Number : 233132

Data Entry Date : 06/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/07/2007

Age :

DOB : 31/12/1981

Outcome :

Causality : Causality possible

Not yet recovered

Information: Patient is hepatitis C positive.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced elevated liver functions whilst on Clozaril therapy.	Clozaril ceased.

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	575 Milligram	Daily	Oral
Batch :	Started : 31/05/2007	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 233142

Data Entry Date : 06/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome : 01/08/2007

DOB : 21/01/1950

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient experienced agranulocytosis whilst on Clopine and a low neutrophil count after ceasing treatment.	Clopine ceased. Given Stimulating factor and IV meropenem.

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	325 Milligram Daily Oral
Batch :	Started : 13/06/2007 Stopped : 27/07/2007
ERYTHROMYCIN (Suspected)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		18/07/2007	6.30	
White blood cells		31/07/2007	4.70	
White blood cells		01/08/2007	9.60	
Neutrophils		18/07/2007	3.50	
Neutrophils		31/07/2007	1.10	
Neutrophils		01/08/2007	4.70	
Other data		18/07/2007	325	Dose(MG)
Other data		31/07/2007	0.0	Dose(MG)
Other data		01/08/2007	0.0	Dose(MG)

Public Case Detail

Cases Count: 393

Case Number : 233156

Data Entry Date : 07/09/2007
Hospitalisation : Admitted to hospital
Onset Date : 09/08/2007
Outcome : 09/08/2007
 Death, maybe drug

Gender : F
Weight (kg) : 0
Age :
DOB : 25/12/1960
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pneumonia	Death	Patient was admitted to hospital with a pneumonia-related illness and died "a few days" later.	

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	750 Milligram	Daily	Oral
Batch :	Started : 15/02/1996	Stopped : 09/08/2007	

Public Case Detail

Cases Count: 393

Case Number : 233291

Data Entry Date : 11/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 11/09/1976

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed low grade cardiomyopathy while on Clozaril.	Clozaril was ceased.

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 01/02/2006	Stopped : 17/08/2007	

Public Case Detail

Cases Count: 393

Case Number : 233311

Data Entry Date : 12/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/08/2007

Age :

DOB : 23/04/1972

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Bowel obstruction. Intestinal obstruction.	

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 20/08/2003	Stopped :	
SODIUM VALPROATE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Case Number : 233404

Data Entry Date : 14/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 14/11/1961

Outcome :

Causality : Causality possible

Recovered

Information: The patient has a history of stomach ulcer before starting treatment. No concomitant medications.
The patient has a history of severe reflux and had previous fundoplication >10 years ago. The patient is also Hepatitis C virus (HCV) positive.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Haematemesis	Incapacity/disability	Following Clopine commencement the patient's reflux symptoms increased. He developed haematemesis.	Ceased Clopine treatment.
Condition aggravated	Incapacity/disability		

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
Batch :	Started : 16/08/2006 Stopped : 01/06/2007
FLUOXETINE HYDROCHLORIDE (Other drug)	Reason : Depression
	20 Milligram Daily Oral
Batch :	Started : Stopped :
METOCLOPRAMIDE HYDROCHLORIDE (Other drug)	Reason : Nausea and vomiting
	30 Milligram Daily Oral
Batch :	Started : Stopped :
MULTIVITAMINS (Other drug)	Reason :
Batch :	Started : Stopped :
THIAMINE (Other drug)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 233411

Data Entry Date : 14/09/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 11/03/1984

Outcome :

Causality : Causality possible

Unknown

Information: The patient's white cell and neutrophil counts were generally within the normal ranges, however, occasional high counts had been reported.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures while on treatment with Clopine.	Clopine was ceased.

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

100 Milligram

Daily

Oral

Batch :

Started : 16/05/2005

Stopped : 17/08/2007

Public Case Detail

Cases Count: 393

Case Number : 233425

Data Entry Date : 17/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/08/2007

Age :

DOB : 09/02/1930

Outcome : 21/08/2007

Causality : Causality possible

Death

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient died of a suspected heart attack.	

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	100 Milligram Daily Oral
Batch :	Started : 08/03/2007 Stopped : 21/08/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils				Patient's neutrophil counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.
White blood cells				Patient's white blood cell counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.

Public Case Detail

Cases Count: 393

Case Number : 233546

Data Entry Date : 19/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 02/09/1961

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced Myocarditis in August 2007. The patient's white blood cell and neutrophil counts were within normal ranges for the treatment period.	Ceased Clopine.

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	175 Milligram Daily Oral
Batch :	Started : 08/08/2007 Stopped : 24/08/2007

Public Case Detail

Cases Count: 393

Case Number : 233552

Data Entry Date : 19/09/2007

Gender : F

Hospitalisation : Required a specialist consultation

Weight (kg) : 0

Onset Date : 25/07/2007

Age :

DOB : 05/08/1957

Outcome :

Causality : Causality possible

Not yet recovered

Information: Patient's white blood cell counts and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Psoriasis	Caused or prolonged inpatient hospitalisation	Whilst on Clopine and Rulide treatment, patient developed acute psoriasis which was reported to be severe in intensity. Psoriasis gradually developed to a severe rash over trunk, upper and lower limbs and face.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified psychosis	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 20/06/2007	Stopped : 31/08/2007	
RULIDE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
LITHIUM CARBONATE (Other drug)		Reason : Unspecified psychosis	
Tablet	1 Gram	Daily	Oral
Batch :	Started :	L TERM	Stopped :

Case Number : 233682

Data Entry Date : 21/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 06/05/1981

Outcome :

Causality : Causality possible

Unknown

Information: Patient was not strict with diabetic diet (ate sweets and chocolates therefore BSL's were fluctuating).

Reaction :

Preferred Term	Severity	Report Description	Treatment
Type 1 diabetes mellitus	Caused or prolonged inpatient hospitalisation	Insulin Dependent Diabetes, creatine kinase high, morning sedation, ecg abnormal, Tachycardia, White blood cell count increased and neutrophils increased.	Protaphane MC, ceased Clozapine. Switched to aripiprazole and commenced amisulpride and valproate.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Blood glucose increased	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	100 Milligram Daily Oral
Batch :	Started : 05/08/2003 Stopped : Contin

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum glucose				Lab tests conducted throughout the patients treatment showed his blood sugar levels range from 8.7 - 15.9 mmols (ref 4-8)

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				ECG on 5 May 2006 showed increased sinus rate of approximately 115 bpm. Pulse varied from 87 - 122 bpm.
Creatine phosphokinase				28 Mar 2006, CK ranged from 621 - 728 U/L (ref 0 - 270)
Neutrophils				Neutrophils were $13.00 \times 10^9/L$ (ref 1.8 - 7.5)
Serum drug level				29 Nov 2006 - Clozapine level : 230
White blood cells				WBC ranged from 11.5 - 17.7 (ref 4.0 - 11.0)

Public Case Detail

Cases Count: 393

Case Number : 233889

Data Entry Date : 02/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 12/07/1967

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced treatment with Clopine on 16 Aug 2007. During the up-titration the patient developed myocarditis. White blood cell counts and neutrophil counts were within normal ranges for the treatment period.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 16/08/2007	Stopped :	05/09/2007

Public Case Detail

Cases Count: 393

Case Number : 233890

Data Entry Date : 02/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 10/10/1975

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Patient developed a CK level of 6008 in Aug/Sep 2007, "since 13 days at 150mg daily" Clozaril.	

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	150 Milligram	Daily	Oral
Batch :	Started : 13/04/2004	Stopped : 21/02/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase				Aug 2007 CK: normal. Aug/Sep 2007 CK: 6008.

Case Number : 233948

Data Entry Date : 02/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 23Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information: The patient underwent pre-clozapine investigations, including an electrocardiogram, echocardiograph, full blood count, hepatic and renal function tests, creatine kinase and troponin I, a CT scan of the brain and electroencephalograph, all of which were normal. Varambally S, Howpage P. Acute myocarditis associated with clozapine. Australian Psychiatry; Aug 2007, 15(4): 343-346.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, chest pain, heart rate increased, tachycardia, chest discomfort, body temperature increased, troponin increased, blood creatine phosphokinase increased, C-reactive protein increased, dyspnoea, white blood count increased.	All psychiatric medications were ceased. He was placed on low doses of bisoprolol and ramipril by the cardiac team.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Body temperature increased	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Heart rate increased	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Reaction :

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

12.5 Milligram Daily

Batch :

Started :

Stopped :

0

FLUOXETINE HYDROCHLORIDE (Suspected)

Reason : Depression

Batch :

Started :

Stopped :

LITHIUM CARBONATE (Suspected)

Reason : Depression

Batch :

Started :

Stopped :

OLANZAPINE (Other drug)

Reason :

15 Milligram

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Heart Rate				Heart rate 160/min
Temperature				Body temperature 38.4
Troponin				Troponin I 10.37 (range up to 0.1).
Creatine phosphokinase				Creatine kinase 259 (range up to 171).
C-Reactive Protein				C-Reactive protein 43.2 (range up to 5.0).

Public Case Detail

Cases Count: 393

Case Number : 233965

Data Entry Date : 03/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 08/11/1978

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		28 year old male commenced Clopine treatment on approximately 13 Aug 2007 and was taking an unknown dose when he experienced myocarditis.	Clopine treatment was ceased.

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
Tablet		1 Dose Unspec Daily	Oral
Batch :	Started : 13/08/2007	Stopped : 03/09/2007	

Public Case Detail

Cases Count: 393

Case Number : 233982

Data Entry Date : 03/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/08/2007

Age :

DOB : 07/06/1963

Outcome : 15/08/2007

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died while being treated with Clopine therapy.	

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 15/11/2001	Stopped :	15/08/2007

Public Case Detail

Cases Count: 393

Case Number : 233983

Data Entry Date : 03/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/09/2007

Age :

DOB : 15/09/1965

Outcome : 05/09/2007

Causality : Causality possible

Death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died due to unexplained reasons whilst being treated with Clopine.	

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 19/10/2004	Stopped :	05/09/2007

Case Number : 234130

Data Entry Date : 08/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/02/2003

Age :

DOB : 20/07/1948

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ureteric obstruction		Patient experienced bilateral ureteric criteria, hydronephrosis, blood creatinine increased, blood phosphorus decreased, blood urea increased, blood albumin decreased, creatine phosphokinase increased, blood calcium decreased, colonic faecal loading, abdominal distension, bladder cancer, hepatic function abnormal. unwell, vomiting.	Clozaril ceased.
Abdominal distension			
Bladder cancer			
Blood albumin decreased			
Blood calcium decreased			
Blood creatine phosphokinase increased			
Blood creatinine increased			
Blood phosphorus decreased			
Blood urea increased			
Faecaloma			
Hepatic function abnormal			
Hydronephrosis			
Malaise			
Vomiting			

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	12 Milligram	Daily	Oral
Batch :	Started : 15/08/1994	Stopped : 25/03/2003	

Public Case Detail

Cases Count: 393

Case Number : 234133

Data Entry Date : 08/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 13/01/1976

Outcome :

Causality : Causality possible

Death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Tachycardia	Death	Patient experienced tachycardia and suspected cardiac re-entry problem.	
Cardiac disorder	Death		

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	425 Milligram	Daily	Oral
Batch :	Started : 02/05/2007	Stopped :	

Case Number : 234231

Data Entry Date : 11/10/2007

Gender : M

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date : 17/09/2007

Age :

DOB : 05/11/1976

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia		Whilst on Clozaril, the patient experienced tachycardia, increased temperature of (38.9c) and hypertension.	
Hypertension			
Pyrexia			

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	400 Milligram Daily Oral
Batch :	Started : 17/11/2005 Stopped : Ongoing.
DIAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
ENDEP (Other drug)	Reason :
Batch :	Started : Stopped :
EPILIM (Other drug)	Reason :
Batch :	Started : Stopped :
RISPERDAL (Other drug)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 234232

Data Entry Date : 11/10/2007
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 11/02/1964
Causality : Causality possible

Information: Patient's white blood cell and neutrophil counts were within normal limits for the treatment period with exception of a few mildly raised results.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Patient developed pneumonia whilst on Clopine therapy.	Treated in intensive care unit.

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 19/01/2004	L TERM	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 234243

Data Entry Date : 11/10/2007

Hospitalisation :

Onset Date : 16/09/2007

Outcome :
Unknown

Gender : F

Weight (kg) : 0

Age :

DOB : 08/02/1968

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased	Caused or prolonged inpatient hospitalisation	Patient commenced Clozaril treatment in Sept 07 for schizophrenia. The patient's dose was currently being titrated. On 16 Sept 07 the patient experienced decreased white blood cell count.	Ceased Clozaril
Neutropenia	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	1 Dose Unspec	Daily	Oral
Batch :	Started : 13/09/2007	Stopped : 16/09/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11)	18/09/2007	2.90	
White blood cells	(4.5-11)	25/09/2007	4.70	
Neutrophils	(1.8-7)	16/09/2007	1.30	
Neutrophils	(1.8-7)	25/09/2007	2.60	

Case Number : 234246

Data Entry Date : 11/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/09/2007

Age :

DOB : 20/06/1958

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Viral infection	Caused or prolonged inpatient hospitalisation	Patient was taking Clozaril for the treatment of Schizophrenia. On 18 Sep 07 the patient experienced fever, viral symptoms, and a decreased white blood cell count.	Clozaril was ceased.
Neutropenia	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	12 Milligram	Daily	Oral
Batch :	Started : 20/01/1999	Stopped :	18/09/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11)	15/09/2007	2.95	
Neutrophils		18/09/2007	0.84	

Case Number : 234260

Data Entry Date : 11/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 13/09/2007

Age :

DOB : 27/09/1951

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced flu like symptoms and vomiting. The patient was detected to have blood creatine phosphokinase increased, troponin T increased, C-reactive protein increased and myocarditis.	Treatment ceased 17/09/07.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Troponin T increased	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet

200 Milligram

Daily

Oral

Batch :

Started : 30/08/2007

Stopped : 17/09/2007

Abilify (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		17/09/2007	1156	
Troponin		17/09/2007	0.201	
C-Reactive Protein		17/09/2007	336	

Case Number : 234262

Data Entry Date : 11/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/09/2007

Age :

DOB : 14/10/1975

Outcome : 19/09/2007

Causality : Causality probable

Recovered

Information: The reporter indicated that all pre-clozapine tests (including WCC and neutrophil count) were normal

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient commenced Clopine treatment on 6 Sept 07. On 9 Sept 07 she presented to the ED with flu like symptoms and a high fever. She was assessed and found to have a 'spot on her lungs' and diagnosed with pneumonia. She was discharged home with a course of antibiotics. Her symptoms deteriorated further. She had a persistent wet cough, productive of green sputum and feeling very lethargic and feverish. The patient returned to the Clinic for her day 7 Clopine review. On examination, she was very tired, irritable and pale. There was a postural drop in her BP and she had tachycardia.	Ceased Clopine. Amoxicillin. IV antibiotics.
Lethargy	Caused or prolonged inpatient hospitalisation		
Leukopenia	Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		
Pneumonia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 150 Milligram Daily Oral

Batch : Started : 06/09/2007 Stopped : 13/09/2007

Risperdal Consta (Other drug)

Reason : Unspecified schizophrenia

Injection 62.5 Milligram Fortnightly Intramuscular

Batch : Started : Stopped : Contin

SODIUM VALPROATE (Other drug)

Reason :

1.5 Gram Oral

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		13/09/2007	3.70	
White blood cells		19/09/2007	6.70	
Neutrophils		13/09/2007	1.87	
Neutrophils		19/09/2007	3.40	

Public Case Detail

Cases Count: 393

Case Number : 234263

Data Entry Date : 11/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/01/1979

Outcome :

Causality : Causality possible

Unknown

Information: The patient's white blood cell (WBC) and neutrophil counts (NC) were slightly elevated around the time of the event.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient commenced Clozapine treatment on 3 July 2001 and switched to Clopine on 30 Nov 2006. The patient's white blood cell and neutrophil counts were slightly elevated around the time of the event.	Ceased Clopine

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	275 Milligram	Daily	Oral
Batch :	Started : 30/11/2006	Stopped :	12/09/2007

Public Case Detail

Cases Count: 393

Case Number : 234264

Data Entry Date : 11/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/09/2007

Age :

DOB : 03/09/1971

Outcome :

Causality : Causality possible

Not yet recovered

Information: The patient's white blood cell and neutrophil counts were elevated on a number of occasions throughout her treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Patient developed pneumonia whilst on Clopine.	Admitted to the intensive care unit, required intubation.

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 04/01/2007	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		01/02/2007	22.9	
White blood cells		15/08/2007	13.5	
Neutrophils		01/02/2007	19.0	
Neutrophils		15/08/2007	9.2	

Public Case Detail

Cases Count: 393

Case Number : 234265

Data Entry Date : 11/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/09/2007

Age :

DOB : 12/01/1978

Outcome : 05/09/2007

Causality : Causality possible

Death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient commenced Clozapine on 21 Sept 2005 and switched to Clopine on 26 Sept 2006. He titrated up to a dose of 300mg daily and continued treatment until his death on 5 Sept 2007.	

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 26/09/2006	Stopped :	05/09/2007

Case Number : 234372

Data Entry Date : 15/10/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/03/1988

Outcome :

Causality : Causality possible

Unknown

Information: History: mental impairment, deterioration of mental state, predominantly hearing voices and velo-cardio-facial syndrome.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular	Caused or prolonged inpatient hospitalisation	Patient experienced a mildly dilated left ventricle, irregular heart rate, blood pressure fluctuation, anaemia, infection, C-reactive protein increased, red blood cell sedimentation rate increased, pyrexia, blood creatine phosphokinase increased, hypoparathyroidism, hypocalcaemia, metal impairment, lower respiratory tract infection, white blood cell count decreased, neutropenia and lymphocyte count decreased.	
Anaemia	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Blood pressure fluctuation	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Heart rate irregular	Caused or prolonged inpatient hospitalisation		
Hypocalcaemia	Caused or prolonged inpatient hospitalisation		
Hypoparathyroidism	Caused or prolonged inpatient hospitalisation		
Infection	Caused or prolonged inpatient hospitalisation		

Reaction :

Preferred Term	Severity	Report Description	Treatment
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Mental impairment	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell sedimentation rate increased	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet

75 Milligram

Daily

Oral

Batch :

Started : 20/03/2006

Stopped : 25/05/2006

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Magnetic Resonance Imaging				Magnetic resonance imaging (MRI) changes suggesting white matter lesions.

Case Number : 234386

Data Entry Date : 15/10/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 12/04/2007

Age :

DOB : 08/04/1954

Outcome :

Causality : Causality possible

Unknown

Information: History: smoker, obesity, diabetes mellitus and hypercholesterolaemia.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Iron deficiency anaemia	Caused or prolonged inpatient hospitalisation	Patient developed anaemia, mean cell haemoglobin decreased, heamoglobin decreased, haematocrit decreased, red blood cell count decreased, mean cell volume decreased, mental disorder, echocardiogram abnormal, troponin 1 increased, hypoxia, fatigue, respiratory tract infection, pyrexia, blood sodium increased, blood chloride decreased, blood potassium decreased, anion gap increased, blood urea increased, blood magnesium decreased and lymphocyte count decreased.	Clozaril ceased. Treated with IV ceftriaxone, azithromycin, augmentin DF and doxycycline.
Anion gap increased	Caused or prolonged inpatient hospitalisation		
Blood chloride decreased	Caused or prolonged inpatient hospitalisation		
Blood magnesium decreased	Caused or prolonged inpatient hospitalisation		
Blood potassium decreased	Caused or prolonged inpatient hospitalisation		
Blood sodium increased	Caused or prolonged inpatient hospitalisation		
Blood urea increased	Caused or prolonged inpatient hospitalisation		
Echocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Fatigue	Caused or prolonged inpatient hospitalisation		

Reaction :

Preferred Term	Severity	Report Description	Treatment
Haematocrit decreased	Caused or prolonged inpatient hospitalisation		
Haemoglobin decreased	Caused or prolonged inpatient hospitalisation		
Hypoxia	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Mean cell haemoglobin decreased	Caused or prolonged inpatient hospitalisation		
Mean cell volume decreased	Caused or prolonged inpatient hospitalisation		
Mental disorder	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell count decreased	Caused or prolonged inpatient hospitalisation		
Respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet 12.5 Milligram Daily Oral
Batch : Started : 29/04/2002 Stopped : 16/08/2007

ASPIRIN (Other drug)

Reason :

Batch : Started : Stopped : Oral

COLOXYL WITH SENNA (Other drug)

Reason :

Tablet Batch : Started : Stopped : Oral

FRUSEMIDE (Other drug)

Reason :

Batch : Started : Stopped :

GLICLAZIDE (Other drug)

Reason :

Tablet Batch : Started : Stopped : Oral

GLYCERYL TRINITRATE (Other drug)

Reason :

Batch : Started : Stopped :

Medicine details :

METFORMIN HYDROCHLORIDE (Other drug)

Reason :

Tablet

Oral

Batch :

Started :

Stopped : 16/08/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		16/07/2004	Mild calcified aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Echocardiogram		18/08/2005	Moderate aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Echocardiogram		05/01/2006	Borderline to severe aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Echocardiogram		12/04/2007	Mild left atrial enlargement severe aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Sodium	(135-145)	17/08/2007	146 mmol/L	
Sodium	(135-145)	18/08/2007	150 mmol/L	
Potassium	(3.5-5.0)	17/08/2007	3.2 mmol/L	
Troponin	(<0.040)	16/08/2007	0.839 ug/L	Troponin 1
Troponin	(<0.040)	16/08/2007	0.873 ug/L	Troponin 1
Troponin	(<0.040)	17/08/2007	0.778 ug/L	Troponin 1

Public Case Detail

Cases Count: 393

Case Number : 234431

Data Entry Date : 16/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 23/08/2007

Age :

DOB : 31/07/1986

Outcome :

Causality : Causality possible

Not yet recovered

Information: Current condition substance abuse alcohol and drugs.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased		Patient experienced elevated liver enzymes.	Clozaril dose was decreased.

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 19/07/2007	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
AST = SGOT	(5-40)	24/08/2007	90	
ALT = SGPT	(5-40)	24/08/2007	204	
GGT = SGGT = GGTP	(1-65)	24/08/2007	99	

Public Case Detail

Cases Count: 393

Case Number : 234547

Data Entry Date : 18/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/06/2007

Age :

DOB : 22/05/1981

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Patient experienced eosinophilia.	Clozaril was ceased.

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 23/05/2007	Stopped : 02/07/2007	
SODIUM VALPROATE (Other drug)		Reason :	
Batch :	Started : 01/06/2007	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Eosinophils		03/04/2007	0.6	
Eosinophils		18/06/2007	1.5	
Eosinophils		29/06/2007	8.2	

Public Case Detail

Cases Count: 393

Case Number : 234552

Data Entry Date : 18/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 31/08/2007

Age :

DOB : 21/02/1945

Outcome : 31/08/2007

Causality : Causality possible

Death, maybe drug

Information: Severe parkinson's disease (end stage) with severe physical disability requiring nursing home care since 2005. He had deafness and a long history of schizophrenia.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Death	Patient experienced a cerebrovascular accident.	

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 06/04/2006	Stopped : 31/08/2007	
DIAZEPAM (Suspected)		Reason :	
Tablet	4 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 234561

Data Entry Date : 18/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2007

Age :

DOB : 25/10/1971

Outcome :

Causality : Causality possible

Unknown

Information: White blood cell counts (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient was taking Clopine 50mg daily at time of Myocarditis.	Ceased treatment with Clopine

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 11/09/2007	Stopped : 26/09/2007	

Public Case Detail

Cases Count: 393

Case Number : 234562

Data Entry Date : 18/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 54.5

Onset Date : 14/09/2007

Age :

DOB : 29/06/1942

Outcome : 17/09/2007

Causality : Causality probable

Unrelated death

Information: Her white blood cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient had previous low grade fever while treated with Clopine. Patient was on dose of 150mg when she experienced echocardiogram which showed mild increase in septal thickness.	Discontinued Clopine
Echocardiogram abnormal			
Pyrexia			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	150 Milligram	Daily	Oral
Batch :	Started : 30/08/2007	Stopped : 17/09/2007	

Public Case Detail

Cases Count: 393

Case Number : 234563

Data Entry Date : 18/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/09/2007

Age :

DOB : 23/09/1976

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient commenced treatment with Clozapine and switched to Clopine on 10 Nov 2006. He was taking 900mg daily at the time of Neutropenia, leucopenia.	Ceased Clopine
Neutropenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	900 Milligram	Daily	Oral
Batch :	Started : 10/11/2006	Stopped : 26/09/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		21/09/2007	3.50	
White blood cells		26/09/2007	2.40	
White blood cells		27/09/2007	2.40	
White blood cells		30/09/2007	2.50	
Neutrophils		21/07/2007	1.52	
Neutrophils		26/09/2007	1.52	
Neutrophils		27/09/2007	0.60	
Neutrophils		30/09/2007	0.66	

Public Case Detail

Cases Count: 393

Case Number : 234564

Data Entry Date : 18/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/09/2007

Age :

DOB : 21/07/1964

Outcome :

Causality : Causality possible

Not yet recovered

Information: The patient's white blood cell and neutrophil count were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Patient experienced confusion and delirium while on Clopine therapy. On admission to hospital patient had a fever and was also found to be tachycardic and hypotensive. Myocarditis was suspected.	IV ceftriaxone. Augmentin.
Delirium	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	400 Milligram Daily Oral
Batch :	Started : 24/04/2007 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				There were no changes in the electrocardiogram (ECG).

Public Case Detail

Cases Count: 393

Case Number : 234631

Data Entry Date : 22/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 05/09/1989

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient experienced pericarditis, tachycardia, increased CK, eosinophilia, weight gain and hypersalivation.	Clozaril discontinued.
Blood creatine phosphokinase increased			
Eosinophilia			
Salivary hypersecretion			
Tachycardia			
Weight increased			

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 17/09/2007	Stopped : 03/10/2007	

Case Number : 234634

Data Entry Date : 22/10/2007

Hospitalisation : Required a visit to the doctor

Onset Date :

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 23/01/1981

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Routine check up including chest X-ray showed cardiomyopathy. Patient had no symptoms. ECG - sinus tachycardia. Clozapine induced Myocarditis.	
Electrocardiogram abnormal			
Myocarditis			
Sinus tachycardia			

Medicine details :			
CLOZAPINE (Suspected)		Reason : Unspecified psychosis	
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
DIABEX (Other drug)		Reason : Diabetes mellitus	
Tablet	1 Gram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Creatine phosphokinase				Normal
Troponin				Normal
Chest X-ray				Showed cardiomyopathy.

Public Case Detail

Cases Count: 393

Case Number : 234641

Data Entry Date : 22/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/10/2007

Age :

DOB : 12/04/1978

Outcome :

Causality : Causality possible

Unknown

Information: White blood cell counts (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced Clopine on 15 August 2007 and ceased treatment due to myocarditis.	Ceased treatment

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	275 Milligram	Daily	Oral
Batch :	Started : 15/08/2007	Stopped : 04/10/2007	

Public Case Detail

Cases Count: 393

Case Number : 234642

Data Entry Date : 22/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 04/01/1967

Outcome :

Causality : Causality possible

Unknown

Information: White blood cells (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	The patient commenced treatment with Clozapine on 29 Oct 2002 and switched to Clopine on 24 Feb 2004. He was taking a dose of 800mg daily and ceased treatment on 3 October due to cardiomyopathy.	Ceased treatment. Treated in ICU.

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 29/10/2002	Stopped :	03/10/2007

Case Number : 234648

Data Entry Date : 22/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2007

Age :

DOB : 14/08/1962

Outcome :

Causality : Causality possible

Not yet recovered

Information: Other drug taken: Acetylsalicylate Calcium. History of diabetes, hyperlipidaemia and mild left ventricular hypertrophy. Patient's white blood cell and neutrophil counts have been within limits for the treatment period with the exception of a few mildly raised results. Patient has been on clozapine for 14 years and the reporter noted that patient is of high coronary risk. He also has diabetes and hyperlipidaemia. Patient has had no previous cardiac problems with normal left ventricular function on previous echocardiograms (Echo) in 2005 and 2006. Echo in 2005 suggested mild left ventricular hypertrophy.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient experienced an enlarged heart whilst on Clopine treatment, mild cardiac enlargement and left pleural effusion, anaemia, rouleaux, left ventricular hypertrophy, neutrophil toxic granulation and abnormal ecg.	Clopine ceased.
Anaemia			
Cardiomegaly			
Electrocardiogram abnormal			
Left ventricular hypertrophy			
Myocarditis			
Neutrophil toxic granulation present			
Pleural effusion			
Rouleaux formation			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
Batch :	Started : 27/04/1993 L TERM Stopped : 02/10/2007 0
ATORVASTATIN (Other drug)	Reason :
Tablet	Oral
Batch :	Started : Stopped :
Glucovance 500/2.5 (Other drug)	Reason :
Tablet	Oral
Batch :	Started : Stopped :

Medicine details :		
ROSIGLITAZONE (Other drug)	Reason :	
Tablet		Oral
Batch :	Started :	Stopped :

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				(CXR) was completed (15/09/07) suggesting mild cardiac enlargement and left pleural effusion. (CXR) 10 days later (25/09/07) showed 'massively enlarged' heart including left atrium and both ventricles, but no pleural effusion.
White blood cells		01/10/2007	12.3 x 10 ⁹ /L	
Neutrophils		01/10/2007	8.9 x 10 ⁹ /L	
Haemoglobin		01/10/2007	11.7	Hb

Case Number : 234689

Data Entry Date : 23/10/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 15/08/2007

Age :

DOB : 06/07/1952

Outcome :

Causality : Causality possible

Recovered

Information: Past history of heavy alcohol use, sensitivity to penicillin (facial swelling). Known history of non compliance with medication.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Patient experienced cardiac complications, was diagnosed with cardiomyopathy, hypokinesia left atrial enlargement, and progressive left ventricular failure.	Clozaril discontinued. Treated with Carvedilol 3.125mg/twice daily.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Left atrial dilatation	Caused or prolonged inpatient hospitalisation		
Left ventricular failure	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet 150 Milligram Daily Oral

Batch : Started : 28/04/2007 Stopped : 15/08/2007

OLANZAPINE (Other drug)

Reason :

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	(0-240)	16/08/2007	51	Pretreatment CK = 44. Global systolic function of 50%. On the 16/08/07 the patient's creatine Kinase (CK) was measured within reference range.

Public Case Detail

Cases Count: 393

Case Number : 234723

Data Entry Date : 23/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/04/1962

Outcome :

Causality : Causality possible

Unknown

Information: These symptoms are in contrast to the normal echocardiogram one month ago.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient presented tachycardic, clammy and sweating. We was febrile, lethargic, unwell and had decreased intake. The doctor diagnosed the patient with having suspected myocarditis.	
Blood creatine phosphokinase increased			
Lethargy			
Pyrexia			
Tachycardia			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecifid affective psychosis
Tablet	200 Milligram Daily Oral
Batch :	Started : 19/09/2007 Stopped :
CARBAMAZEPINE (Other drug)	Reason : Unspecifid affective psychosis
Tablet	200 Milligram Daily Oral
Batch :	Started : Stopped : 0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood pressure				148 bpm.
Troponin				0.38
Creatine phosphokinase				CK 170
White blood cells				White blood cell and neutrophil counts were normal throughout the treatment period.

Public Case Detail

Cases Count: 393

Case Number : 234736

Data Entry Date : 23/10/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 09/10/2007

Age :

DOB : 07/04/1948

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pneumonia aspiration	Caused or prolonged inpatient hospitalisation	Patient was hospitalised for a bowel obstruction and pneumonia and suffered from constipation.	Clozaril temporarily ceased for more than 4 days.
Constipation	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		
Red cell distribution width increased	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 23/12/1999	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Lymphocytes	(1.2 - 4.0 x 10 ⁹ /L)	09/10/2007	04x10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 234773

Data Entry Date : 25/10/2007

Gender : M

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/03/1977

Outcome :

Causality : Causality possible

Unknown

Information: History of raised white cell counts whilst being treated with Clopine.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Caused or prolonged inpatient hospitalisation	Patient experienced acute abdominal pain and was taken to emergency department. The patient was found to have faecal impaction and upon further investigation, a bowel perforation.	Admitted to Intensive Care Unit..
Faecaloma	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	425 Milligram Daily Oral
Batch :	Started : 26/07/2007 Stopped :

Public Case Detail

Cases Count: 393

Case Number : 234789

Data Entry Date : 25/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 11/02/1970

Outcome :

Causality : Causality possible

Unknown

Information: The patient's white blood cell and neutrophil counts were above the normal ranges throughout treatment, though baseline levels were also elevated.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced Clopine treatment and developed myocarditis.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 25/09/2007	Stopped : 11/10/2007	

Case Number : 234938

Data Entry Date : 01/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/09/2007

Age :

DOB : 09/02/1957

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Patient commenced Clopine treatment on 20 Aug 2007. On 5 Sept 2007 the patient was found to have a high grade fever and mild pedal oedema. Patient was tachycardic and his troponin T, creatine kinase and c-reactive protein were all elevated. Patient was therefore clinically diagnosed to have acute cardiac failure, however the reporting medical practioner considered the underlying cause to be myocarditis. Patient also had low haemoglobin. Red cells showed increased rouleaux. Also marked eosinophilia.	Frusemide, perindopril, carvedilol and cessation of Clopine.
Blood creatine phosphokinase increased	Life threatening		
Cardiac failure	Life threatening		
Eosinophilia	Life threatening		
Haemoglobin decreased	Life threatening		
Oedema peripheral	Life threatening		
Pyrexia	Life threatening		
Rouleaux formation	Life threatening		
Tachycardia	Life threatening		
Troponin T increased	Life threatening		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	275 Milligram	Daily	Oral
Batch :	Started : 21/08/2007	Stopped : 07/09/2007	

Medicine details :

RISPERIDONE (Other drug)

Reason :

Injection

Batch :

Started : 01/03/2007

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Ejection fraction		05/09/2007	31%	

Public Case Detail

Cases Count: 393

Case Number : 234959

Data Entry Date : 01/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/10/2007

Age :

DOB : 27/05/1936

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient had a chest infection. White blood cell count decreased while being treated with Clozaril.	Antibiotics
Lower respiratory tract infection			
Neutrophil count decreased			

Medicine details :			
CLOZAPINE (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 21/06/2006	Stopped : 08/10/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		10/10/2007	2.40 (reference 4.5-11 x 10 ⁹ /L)	
White blood cells		09/10/2007	2.80	
White blood cells		08/10/2007	3.00	
Neutrophils		08/10/2007	0.70 (reference 1.8-7.7x10 ⁹ /L)	
Neutrophils		08/10/2007	1.70	
Neutrophils		08/10/2007	1.90	

Public Case Detail

Cases Count: 393

Case Number : 234993

Data Entry Date : 02/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 13/04/1963

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion	Caused or prolonged inpatient hospitalisation	Patient was hospitalised for "gastro" and had developed eosinophilla. The patient also had "a tiny myocardial effusion". It was also noted that the patient had "myoclonic jerks - facial". These symptoms had coincided with the addition of ciprofloxacin for the gastro.	
Myoclonus	Caused or prolonged inpatient hospitalisation		

Medicine details :

CIPROFLOXACIN (Suspected)		Reason :	
		1 Dose Unspec Daily	
Batch :	Started :	Stopped :	
CLOZARIL (Suspected)		Reason :	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 27/07/2007	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 235006

Data Entry Date : 02/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/10/2007

Age :

DOB : 15/06/1970

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Influenza like illness		Patient complaining of aching pains, documented postural hypotension since Clozapine initiation, tachycardia, development of flu-like symptoms.	Clozapine ceased. Metoprolol started. Pt referred to ED for cardiology.
Orthostatic hypotension			
Tachycardia			

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral	
Batch :	Started : 11/10/2007	Stopped : 23/10/2007	0	
RISPERIDONE (Other drug)		Reason : Unspecified schizophrenia		
Tablet	37.5 Milligram	Daily	Oral	
Batch :	Started :	Stopped :		

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		23/10/2007	0.25	
Troponin		24/10/2007	0.24	
Troponin		25/10/2007	0.16	

Public Case Detail

Cases Count: 393

Case Number : 235016

Data Entry Date : 05/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Patient developed Addison's disease and orthostatic hypotension whilst being treated with Clopine.	
Addison's disease			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	650 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Blood pressure				low

Public Case Detail

Cases Count: 393

Case Number : 235034

Data Entry Date : 05/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 11/11/1984

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Patient was taking Clozaril since 8 October 2003. The reporter stated that the patient had missed nine days of treatment. The physician conducted routine blood tests and this indicated that the patient's CK levels had risen sharply.	

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 08/10/2003	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/08/2007	305	(Date not provided, recen test) CK:1341.
White blood cells				White blood cells count were all within normal range.
Neutrophils				Neutrophil count levels were all within normal range.
Troponin				Troponin levels were all within normal range.

Public Case Detail

Cases Count: 393

Case Number : 235035

Data Entry Date : 05/11/2007

Hospitalisation :

Onset Date : 16/10/2007

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 26/01/1954

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Lower respiratory tract infection		Patient experienced chest infection and right pleural effusion whilst on Clozaril. The patient's blood tests showed elevated White Blood Cell counts and elevated Neutrophil counts.	
Neutrophil count increased			
Pleural effusion			
White blood cell count increased			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 22/07/1994	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		16/10/2007	38.90	
Neutrophils		16/10/2007	34.80	

Case Number : 235064

Data Entry Date : 07/11/2007
Hospitalisation : Admitted to hospital
Onset Date : 16/10/2007
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 28/03/1977
Causality : Causality possible

Information: Has a temporary colostomy bag.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Constipation	Life threatening	Sudden onset of testicular and abdominal pain which escalated rapidly, with findings of a rigid abdomen. He required surgery - found to be severely constipated with a rupture of the colon and faeces within abdominal cavity.	Surgery.
Large intestine perforation	Life threatening		
Peritonitis	Life threatening		

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	425 Milligram	Daily	Oral
Batch :	Started : 27/07/2007	Stopped : 16/10/2007	0
HALOPERIDOL (Other drug)	Reason : Unspecified schizophrenia		
	20 Milligram	Daily	
Batch :	Started : 18/04/2007	Stopped :	0
LITHIUM CARBONATE (Other drug)	Reason : Unspecified schizophrenia		
	750 Milligram	Daily	
Batch :	Started :	L TERM	Stopped : 0

Public Case Detail

Cases Count: 393

Case Number : 235143

Data Entry Date : 09/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 11/04/1971

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Patient commenced Clozapine on 23 Nov 2006 and switched to Clopine on 12 July 07. Patient experienced a stroke.	Ceased Clopine.

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 12/07/2007	Stopped : 06/10/2007	

Public Case Detail

Cases Count: 393

Case Number : 235264

Data Entry Date : 14/11/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 24/10/2007

Age :

DOB : 09/08/1951

Outcome :

Causality : Causality probable

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Patient experienced a collapse, seizure and increased blood clozapine levels whilst on Clopine treatment.	Clopine dose reduced to 300mg.
Convulsion	Caused or prolonged inpatient hospitalisation		
Drug level above therapeutic	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 18/07/2000	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Serum drug level				A Clozapine blood level was found to be 1365 ug/L and norclozapine 676 ug/L. This was described as 'toxic' by the reporter.

Public Case Detail

Cases Count: 393

Case Number : 235414

Data Entry Date : 19/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/10/2007

Age :

DOB : 14/01/1961

Outcome :

Causality : Causality possible

Unknown

Information: Patient later died from the cardiac event which was not related to Clozaril but was due to an abscess on the heart.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient experienced cardiac complications - pericardial effusion.	Clozaril ceased.

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 10/06/1993	Stopped : 26/10/2007	0

Public Case Detail

Cases Count: 393

Case Number : 235432

Data Entry Date : 20/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/10/2007

Age :

DOB : 15/06/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Left ventricular hypertrophy		Cardiac complications, including left ventricular hypertrophy (shown on echo) and myocarditis.	Ceased therapy.
Echocardiogram abnormal			
Myocarditis			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 11/10/2007	Stopped : 24/10/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Echocardiogram				Echo: Left ventricular hypertrophy, myocarditis.

Case Number : 235460

Data Entry Date : 20/11/2007
Hospitalisation : Admitted to hospital
Onset Date : 08/03/2007
Outcome : 19/03/2007
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 07/11/1940
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Asthenia	Life threatening		
Malaise	Life threatening		
Pneumonia mycoplasmal			doxycycline
Pyrexia	Life threatening		
Tachycardia	Life threatening		

Medicine details :

CLOZAPINE (Suspected)	Reason :
Tablet	200 Milligram Daily Oral
Batch :	Started : 20/02/2007 Stopped : 08/03/2007
EPILIM (Other drug)	Reason :
	500 Milligram
Batch :	Started : Stopped :
OMEPRAZOLE (Other drug)	Reason :
	20 Milligram
Batch :	Started : Stopped :
PARACETAMOL (Other drug)	Reason :
	1 Gram
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				CRP = 174 WCC = 10 ESR high Pathology positive for mycoplasma pneumonia and commenced on doxycycline for 2 weeks 100mg bd
Electrocardiography				TTE showed normal LC size with low normal systolic function

Public Case Detail

Cases Count: 393

Case Number : 235473

Data Entry Date : 21/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/08/2007

Age :

DOB : 13/05/1976

Outcome :

Causality : Causality possible

Unknown

Information: The patient was previously treated with Clopine and ceased treatment due to cardiomyopathy. The patient's white blood cell and neutrophil counts were within acceptable limits for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis and cardiac chest pain.	Ceased clozapine.
Chest pain			

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

37.5 Milligram

Daily

Oral

Batch :

Started : 20/08/2007

Stopped : 24/08/2007

0

Public Case Detail

Cases Count: 393

Case Number : 235498

Data Entry Date : 21/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/10/2007

Age :

DOB : 30/07/1977

Outcome :

Causality : Causality certain

Not yet recovered

Information: Suspected drug is cert/rechallenge. Patient's white cell and neutrophil counts were within the normal ranges throughout treatment. Full blood count, electrolytes, urea and creatinine, liver functions tests, troponin I, urine culture, blood culture and chest x-ray were all normal.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient experienced mild blurred vision, severe high fever of (>39c), severe tachycardia (>150HR) and postural hypotension (90/60).	
Tachycardia			
Vision blurred			

Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 50 Milligram Daily Oral

Batch : **Started :** 10/10/2007 **Stopped :** Continuing.

RISPERIDONE (Other drug)

Reason : Unspecified psychosis

2 Milligram Daily

Batch : **Started :** **Stopped :**

Public Case Detail

Cases Count: 393

Case Number : 235499

Data Entry Date : 21/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/11/2007

Age :

DOB : 29/06/1967

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leukopenia.	Clopine ceased.
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 10/08/2007	Stopped : 05/11/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		06/11/2007	2.30	
White blood cells		05/11/2007	2.10	
White blood cells		23/10/2007	4.60	
Neutrophils		06/11/2007	0.85	
Neutrophils		05/11/2007	0.84	
Neutrophils		23/10/2007	2.51	
Other data		06/11/2007	0.0	Dose
Other data		05/11/2007	0.0	Dose
Other data		23/10/2007	400.0	Dose

Public Case Detail

Cases Count: 393

Case Number : 235500

Data Entry Date : 21/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/10/2007

Age :

DOB : 12/11/1983

Outcome : 29/10/2007

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 03/01/2007	Stopped : 29/10/2007	

Public Case Detail

Cases Count: 393

Case Number : 235503

Data Entry Date : 21/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/10/2007

Age :

DOB : 02/06/1954

Outcome : 26/10/2007

Causality : Causality possible

Unrelated death

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 06/11/2006	Stopped :	

Case Number : 235572

Data Entry Date : 23/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/11/2007

Age :

DOB : 18/08/1966

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient experienced a decrease in his white blood cell count.	Clozaril discontinued.
Agranulocytosis			

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	400 Milligram Daily Oral
Batch :	Started : 01/09/2007 Stopped : 01/11/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 ⁹ L)	01/09/2007	Pre-treatment 6.8x10 ⁹ L	
White blood cells	(4.5-11.0x10 ⁹ L)	01/11/2007	1.30x10 ⁹ L	
White blood cells	(4.5-11.0x10 ⁹ L)	03/11/2007	1.10x10 ⁹ L	
White blood cells	(4.5-11.0x10 ⁹ L)	04/11/2007	1.00x10 ⁹ L	
White blood cells	(4.5-11.0x10 ⁹ L)	05/11/2007	1.60x10 ⁹ L	
White blood cells	(4.5-11.0x10 ⁹ L)	06/11/2007	0.80x10 ⁹ L	
Neutrophils	(1.8-7.7x10 ⁹ L)	01/09/2007	Pre-treatment 3.9x10 ⁹ L	
Neutrophils	(1.8-7.7x10 ⁹ L)	01/11/2007	0.2x10 ⁹ L	
Neutrophils	(1.8-7.7x10 ⁹ L)	03/11/2007	0.10x10 ⁹ L	
Neutrophils	(1.8-7.7x10 ⁹ L)	04/11/2007	0.10x10 ⁹ L	
Neutrophils	(1.8-7.7x10 ⁹ L)	05/11/2007	0.00x10 ⁹ L	
Neutrophils	(1.8-7.7x10 ⁹ L)	06/11/2007	0.00x10 ⁹ L	

Public Case Detail

Cases Count: 393

Case Number : 235580

Data Entry Date : 23/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 99

Age :

Onset Date :

DOB : 10/07/1973

Outcome :

Causality : Causality possible

Not yet recovered

Information: White cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.
Has a history of elevated LFTs to other antipsychotic medications (zuclopenthicol).
At the time of this report the patient had recovered from the episode of AF but the hepatitis remained ongoing.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation	Caused or prolonged inpatient hospitalisation	The patient commenced Clopine on 2 August 2007. He developed progressive hepatitis (severe) and experienced an episode of Atrial Fibrillation (moderate).	Metoprolol, initially digoxin. Ceased Clopine.
Hepatitis	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet

150 Milligram

Daily

Oral

Batch :

Started : 02/08/2007

Stopped : 20/08/2007

Public Case Detail

Cases Count: 393

Case Number : 235597

Data Entry Date : 23/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 24Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Pancreatitis, fever and abdominal pain.	Norfloxacin was discontinued.
Abdominal pain	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
METRONIDAZOLE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
NOROXIN (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 235605

Data Entry Date : 23/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 04/10/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Depression		Whilst on Clozaril the patient experienced depression and hypersalivation.	
Salivary hypersecretion			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 14/08/2007	Stopped :	

Case Number : 235628

Data Entry Date : 26/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age :

DOB : 05/06/1963

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		On an unspecified date, the patient developed a lung infection for which he had been on Doxylin and Augmentin Duo Forte during Oct 2007. It was reported that on 5 Nov 2007 whilst on Clozaril 400mg twice daily, blood tests results showed that the patient's white blood cell count was decreased.	

Medicine details :

AUGMENTIN DUO FORTE (Suspected)	Reason :		
Batch :	Started :	Stopped :	
CLOZARIL (Suspected)	Reason :		
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 15/04/1994	Stopped :	
DOXYLIN (Suspected)	Reason :		
Batch :	Started :	Stopped :	
EPILIM (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		09/10/2007	5.90	
White blood cells		05/11/2007	5	
White blood cells		07/11/2007	4.4	
Neutrophils		09/10/2007	3.10	
Neutrophils		07/11/2007	1.4	

Public Case Detail

Cases Count: 393

Case Number : 235633

Data Entry Date : 26/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 01/08/1979

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Patient's neutrophil count decreased.	Ceased Clozaril.

Medicine details :			
CIPROFLOXACIN (Suspected)		Reason :	
		1 Dose Unspec Daily	
Batch :	Started :	Stopped :	
CLOZARIL (Suspected)		Reason :	
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 20/01/2003	Stopped : 08/11/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		08/10/2007	5.20	
White blood cells		08/11/2007	3.90	
Neutrophils		08/10/2007	2.80	
Neutrophils		08/11/2007	1.20	

Case Number : 235678

Data Entry Date : 26/11/2007

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 08/10/2007

Age :

DOB : 16/08/1969

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Patient experienced a fall in his white cell count and neutrophil count.	Clozapine ceased.
Leukopenia	Life threatening		

Medicine details :

CLOZARIL (Suspected)	Reason : Agranulocytosis		
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 12/04/2007	Stopped : 08/10/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.0-11.0)	08/10/2007	3.5	
White blood cells	(4.0-11.0)	15/10/2007	2.6	
White blood cells	(4.0-11.0)	22/10/2007	2.7	
White blood cells	(4.0-11.0)	02/11/2007	7.1	
Neutrophils	(2.0-8.0)	08/10/2007	1.5	
Neutrophils	(2.0-8.0)	15/10/2007	1.2	
Neutrophils	(2.0-8.0)	20/10/2007	2.7	
Neutrophils	(2.0-8.0)	02/11/2007	3.7	

Public Case Detail

Cases Count: 393

Case Number : 235684

Data Entry Date : 27/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/09/2007

Age :

DOB : 27/07/1981

Outcome : 22/09/2007

Causality : Causality possible

Death

Information: FI provides history of increased suicidal ideation and uncontrolled schizophrenia. Patient confirmed to have been on clozapine, mirtazapine and ranitidine at time of death, but some doubts about compliance have been raised.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Patient completed suicide by hanging.	

Medicine details :

CLOZARIL (Suspected)

Reason :

Tablet

225 Milligram

Daily

Oral

Batch :

Started : 04/10/2006

Stopped : 22/09/2007

Case Number : 235748

Data Entry Date : 28/11/2007

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 25/10/2007

Age :

DOB : 20/12/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute pancreatitis, abdominal pain and fever. Lipase and amylase levels increased. Gastroenteritis.	Clozaril ceased by patient and re-initiated on Clozaril slowly.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Blood amylase increased	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Gastroenteritis	Caused or prolonged inpatient hospitalisation		
Lipase increased	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	125 Milligram Daily Oral
Batch :	Started : 11/10/2007 Stopped :
FLAGYL (Suspected)	Reason :
Batch :	Started : Stopped :
NOROXIN (Suspected)	Reason :
	Daily Oral
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
lipase				Lipase and amylase levels were 'very high'

Case Number : 235820

Data Entry Date : 03/12/2007
Hospitalisation : Admitted to hospital
Onset Date :
Outcome : 25/09/2007
 Death

Gender : M
Weight (kg) : 0
Age :
DOB : 15/10/1954
Causality : Causality possible

Information: The death was sudden and of unknown cause at the time of the report.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Death	Patient experienced pulmonary embolism, sudden death, neuroleptic malignant syndrome, blood creatine phosphokinase increased, antipsychotic drug level increased.	
Antipsychotic drug level increased	Death		
Blood creatine phosphokinase increased	Death		
Neuroleptic malignant syndrome	Death		
Sudden death	Death		

Medicine details :

Abilify (Suspected)		Reason : Unspecified psychosis	
Tablet	15 Milligram	Daily	Oral
Batch :	Started : 15/02/2007	Stopped :	
CLOZARIL (Suspected)		Reason : Unspecified psychosis	
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 25/10/1993	Stopped : 25/09/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/09/2007	933	
Creatine phosphokinase		25/09/2007	2216	
White blood cells		15/09/2007	19	
Serum drug level				10 Nov 2005 Serm clozapine: 574ug/L (on Clozaril dose of 250mg bd)

Public Case Detail

Cases Count: 393

Case Number : 236050

Data Entry Date : 07/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/10/2007

Age :

DOB : 18/04/1973

Outcome :

Causality : Causality possible

Unknown

Information: Treatment with Clopine is continuing.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Subdural haematoma	Caused or prolonged inpatient hospitalisation	Patient experienced subdural haematoma, confusion and headache whilst on Clopine.	ICU. Epilim was ceased. Phenytoin. Craniotomy was performed.
Confusional state	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

Medicine details :

ASPIRIN (Suspected)		Reason : Headache	
		Daily	
Batch :	Started :	Stopped :	0
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	Contin
EPILIM (Suspected)		Reason : Other&unspecified epilepsy	
	600 Milligram	Daily	
Batch :	Started :	Stopped :	0
CLOMIPRAMINE HYDROCHLORIDE (Other drug)		Reason :	
Tablet	150 Milligram		Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				Patient's white blood cell counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.
Neutrophils				Patient's neutrophill counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.

Public Case Detail

Cases Count: 393

Case Number : 236119

Data Entry Date : 11/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 16/07/1973

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced flu-like symptoms, a fever (39 C), generally felt unwell, had vague chest pain and troponin level of 0.1.	
Chest pain			
Malaise			
Pyrexia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 26/10/2007	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells				Patient's white blood cell count have remained within normal ranges over the duration of treatment.
Neutrophils				Patient's neutrophil count have remained within normal ranges form the duration of treatment.t

Public Case Detail

Cases Count: 393

Case Number : 236124

Data Entry Date : 11/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/01/2007

Age :

DOB : 09/03/1972

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced Neutropenia.	Clozapine ceased.

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 26/10/1998	Stopped : 05/10/2007	

Public Case Detail

Cases Count: 393

Case Number : 236369

Data Entry Date : 17/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/11/2007

Age :

Outcome : 21/11/2007

DOB : 28/11/1958

Death

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Acute myocardial infarction	Death	Patient died as a result of an acute myocardial infarction whilst being treated with Clopine.	

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	500 Milligram Daily Oral
Batch :	Started : 08/08/2006 Stopped :

Public Case Detail

Cases Count: 393

Case Number : 236386

Data Entry Date : 18/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/10/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced a pulmonary embolism described as severe in intensity.	ICU. Ceased Clopine.

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	350 Milligram Daily Oral
Batch :	Started : 07/03/2007 Stopped : 30/11/2007

Public Case Detail

Cases Count: 393

Case Number : 236392

Data Entry Date : 18/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 75

Onset Date : 16/08/2007

Age :

DOB : 03/07/1981

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction	Incapacity/disability	Onset of LV global dysfunction	

Medicine details :			
CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Capsule	350 Milligram	1 time	Oral
Batch :	Started : 16/08/2005	Stopped : 16/10/2007	

Public Case Detail

Cases Count: 393

Case Number : 236396

Data Entry Date : 18/12/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/10/1963

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hyperthermia malignant	Caused or prolonged inpatient hospitalisation	Patient developed hyperthermia malignant possibly had an infection.	Discontinuation of Clozaril.
Infection	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 07/11/2007	Stopped : 23/11/2007	

Public Case Detail

Cases Count: 393

Case Number : 236454

Data Entry Date : 20/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 91

Onset Date : 10/11/2007

Age : 34Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction. Intermittent breathlessness and chest pain on exertion now resolved with cessation of clozapine.	Cessation of clozapine.
Cardiomyopathy			
Chest pain			
Dyspnoea			

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 27/08/2007	Stopped : 12/12/2007	
CLOPIXOL (Other drug)		Reason :	
Injection	150 Milligram	Intramuscular	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Echocardiogram result 10/11- Left ventricular dysfunction. Mild to moderate symmetrical or global hypokinesia with his fractional shortening being reduced to 24%. This equates to an ejection of around 44-48%.

Public Case Detail

Cases Count: 393

Case Number : 236510

Data Entry Date : 24/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 04/01/1979

Outcome :

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient commenced treatment with clozapine and switched to Clopine on 21 Nov 2006. Patient was titrated up to a maximum dose of 1050g/PO daily. Prior to the patient's death he was on a stable dose of 675mg/PO daily.	

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	675 Milligram	Daily	Oral
Batch :	Started : 20/08/1998	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 236770

Data Entry Date : 08/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 19/07/1957

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocardial infarction		The patient experienced a heart attack and Ischaemic Heart Disease.	Ceased Clopine
Myocardial ischaemia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 30/10/2007	Stopped : 16/11/2007	

Public Case Detail

Cases Count: 393

Case Number : 236789

Data Entry Date : 09/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 03/01/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed cardiomyopathy whilst on Clozaril.	Clozaril ceased.

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 12/09/1997	Stopped :	26/11/2007

Case Number : 236809

Data Entry Date : 09/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 07/05/2007

Age :

DOB : 23/12/1952

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		On 7 May 2007 whilst on Clozaril, the patient's while blood cells and neutrophil counts were measured low. Clozaril was withheld for one day and resumed with no change. Valproate sodium was added and Clozaril dose increased. On 25 Oct 07 the patient had low blood counts again. Clozaril was discontinued with immediate positive result. The patient had then a severe rebound psychosis, became uncooperative and catatonic at times. She stopped eating and drinking and became dehydrated, despite reasonable doses of typical anti-psychotics intramuscularly.	
Neutrophil count decreased			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	400 Milligram Daily Oral
Batch :	Started : 21/03/2006 Stopped : 25/10/2007 0
SODIUM VALPROATE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	16/03/2006	8.80	
White blood cells	(4.5-11.0)	25/10/2007	3.20	
White blood cells	(4.5-11.0)	31/10/2007	4.90	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	20/11/2007	3.50	
Neutrophils	(1.8-7.7)	16/03/2006	6.24	
Neutrophils	(1.8-7.7)	25/10/2007	1.40	
Neutrophils	(1.8-7.7)	20/11/2007	1.90	

Public Case Detail

Cases Count: 393

Case Number : 236822

Data Entry Date : 09/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/11/2007

Age :

Outcome : 20/11/2007

DOB : 16/02/1971

Death

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Male patient died due to unknown reasons whilst being treated with Clopine.	

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	900 Milligram	Daily	Oral
Batch :	Started : 10/05/2005	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 236824

Data Entry Date : 09/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/10/2007

Age :

DOB : 13/06/1979

Outcome : 15/10/2007

Causality : Causality possible

Death

Information: FI suggests possible intentional overdose because several packets of clozapine found near patient, but overdose is unconfirmed

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died due to unknown reasons whilst being treated with Clopine.	

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 236825

Data Entry Date : 09/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/12/2007

Age :

DOB : 23/10/1956

Outcome : 01/12/2007

Causality : Causality possible

Death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died due to unknown reasons whilst being treated with Clopine.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 05/05/2007	Stopped : 01/12/2007	

Public Case Detail

Cases Count: 393

Case Number : 236872

Data Entry Date : 10/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 14/12/1972

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Sinus tachycardia		Patient developed tachycardia.	
Echocardiogram abnormal			
Electrocardiogram abnormal			
Pericardial effusion			

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 12/09/2007	Stopped :	
AMISULPRIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				Tachycardia:110-130 bpm.
Electrocardiography				Tachycardia ranging 115-138 bpm.

Public Case Detail

Cases Count: 393

Case Number : 236909

Data Entry Date : 11/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/06/2006

Age :

DOB : 20/11/1980

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Heart rate irregular		Patient developed parotid swelling, mild tonsillar erythema, vomiting, productive cough, raised monocytes, sinus tachycardia, palpitations at times, ventricular bigeminy, macular facial and chest rash.	Ceased Clozapine
Palpitations			
Parotid gland enlargement			
Productive cough			
Rash macular			
Sinus bradycardia			
Tonsillar disorder			
Ventricular extrasystoles			
Vomiting			

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	200 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 236944

Data Entry Date : 14/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age :

DOB : 29/06/1948

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced delirium, hypersalivation, altered mental state and fever.	Ceased Clozapine
Delirium			
Mental status changes			
Pyrexia			
Salivary hypersecretion			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily Oral
Batch :	Started : 12/11/2007 Stopped : 30/11/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				White blood cells were within normal ranges.
Neutrophils				Neutrophil counts were within normal ranges throughout treatment.

Public Case Detail

Cases Count: 393

Case Number : 236971

Data Entry Date : 15/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/12/1968

Outcome :

Causality : Causality possible

Unknown

Information: Patient's white blood cell counts (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient had early stage cardiomyopathy and ventricular dilatation.	Ceased Clopine
Dilatation ventricular			

Medicine details :

CLOPINE (Suspected)	Reason :	
Tablet	500 Milligram	Daily
		Oral
Batch :	Started : 20/02/2007	Stopped : 04/12/2007

Case Number : 237151

Data Entry Date : 21/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/12/2007

Age :

DOB : 20/07/1948

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia and leukopenia.	Ceased Clozaril.
Leukopenia			

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	500 Milligram Daily Oral
Batch :	Started : 15/04/1994 Stopped : 04/12/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 ⁹ /L)	15/08/1994	4.6x10 ⁹ /L (pre-treatment)	
White blood cells	(4.5-11.0x10 ⁹ /L)	29/11/2007	5.50x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	04/12/2007	2.60x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	05/12/2007	2.20x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	07/12/2007	2.30x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	10/12/2007	2.00x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	12/12/2007	1.70x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	13/12/2007	1.20x10 ⁹ /L	
White blood cells	(4.5-11.0x10 ⁹ /L)	18/12/2007	1.0 x 10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	15/08/1994	2.8x10 ⁹ /L (pre-treatment)	
Neutrophils	(1.8-11.0x10 ⁹ /L)	29/11/2007	4.20x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	04/12/2007	1.70x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	05/12/2007	1.30x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	07/12/2007	1.00x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	10/12/2007	0.70x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	12/12/2007	0.20x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	13/12/2007	0.10x10 ⁹ /L	
Neutrophils	(1.8-11.0x10 ⁹ /L)	18/12/2007	0.1 x 10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 237206

Data Entry Date : 22/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 01/01/1978

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient was described as having chest pain, breathlessness, muscle aches, tachycardia, increased creatine kinase and suspected myocarditis.	Clozapine ceased.
Blood creatine phosphokinase increased			
Chest pain			
Dyspnoea			
Myalgia			
Tachycardia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 28/05/2007	Stopped : 15/12/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Heart Rate				Parameter: Heart rate: Value = 100-120
Creatine phosphokinase				Parameter: Creatine kinase: Value = 500

Public Case Detail

Cases Count: 393

Case Number : 237211

Data Entry Date : 22/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 16/03/1980

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed cardiomyopathy.	Clozaril discontinued.

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 03/08/2004	Stopped : 10/12/2007	

Public Case Detail

Cases Count: 393

Case Number : 237215

Data Entry Date : 22/01/2008

Gender : M

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date : 27/06/2003

Age :

DOB : 24/05/1963

Outcome :

Causality : Causality possible

Not yet recovered

Information: Historical drug: mood stabilizer without effect.

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased	Caused or prolonged inpatient hospitalisation	Patient's white blood cell count decreased and his neutrophil count decreased.	Clozaril discontinued.
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 05/10/1993	Stopped : 24/06/2003	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		12/05/2003	3.80 x 10 ⁹ /L	
White blood cells		27/06/2003	2.80 x 10 ⁹ /L	
White blood cells		04/08/2003	13.20 x 10 ⁹ /L	
Neutrophils		12/05/2003	1.70 x 10 ⁹ /L	
Neutrophils		27/06/2003	1.00 x 10 ⁹ /L	
Neutrophils		04/08/2003	9.10 x 10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 237388

Data Entry Date : 29/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 22/05/1976

Outcome :

Causality : Causality possible

Not yet recovered

Information: The treating psychiatrist reported two possible causes of NMS. The first was that the NMS was directly caused by Clopine treatment. The second was hyponatremia caused by venlafaxine and desmopressin, led to seizures which was treated with haloperidol. This chain of events led to NMS.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient commenced treatment with Clopine on 26 March 2007. Patient developed neuroleptic malignant syndrome and 'pseudo pneumonia' (pneumonia due to pseudomonas).	
Convulsion	Caused or prolonged inpatient hospitalisation		
Lung infection pseudomonal	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

450 Milligram

Daily

Oral

Batch :

Started : 26/03/2007

Stopped : 06/01/2008

Public Case Detail

Cases Count: 393

Case Number : 237399

Data Entry Date : 29/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 31/01/1982

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Weight increased	Incapacity/disability	Patient gained 10kg (from 73kg to 83.8kg).	Clozaril discontinued, dietician and exercise for weight control.

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 28/04/2003	Stopped : 14/11/2007	

Public Case Detail

Cases Count: 393

Case Number : 237482

Data Entry Date : 01/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/11/2007

Age :

DOB : 19/09/1973

Outcome :

Causality : Causality possible

Recovered

Information: Cardiologists recommendation who believed the findings were secondary to clozapine.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction, ejection fraction decreased, echocardiogram abnormal, chest pain, shortness of breath.	Ceased Clozaril
Chest pain			
Dyspnoea			
Echocardiogram abnormal			
Ejection fraction decreased			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
Batch :	Started : 28/08/2007 Stopped : 12/12/2007
CLOPIXOL (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Echo: left ventricular dysfunction, ejection fraction 44-48%. No baseline echocardiogram was performed prior to the start of Clozaril treatment.

Case Number : 237502

Data Entry Date : 04/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 07/12/2007

Age :

DOB : 22/06/1959

Outcome :

Causality : Causality possible

Recovered

Information: White blood cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Patient experienced a severe tonic-clonic seizure lasting approximately 3 minutes including myoclonic activity and loss of consciousness. She had another complex partial seizure in the right side of her face lasting approximately 2 minutes.	Clopine ceased
Complex partial seizures			

Medicine details :

AMISULPRIDE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 01/10/2007	Stopped :	
CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	750 Milligram	Daily	Oral
Batch :	Started : 05/09/2007	Stopped : 19/12/2007	0
ASPIRIN (Other drug)	Reason :		
Batch :	Started :	Stopped :	
ATORVASTATIN (Other drug)	Reason :		
Batch :	Started :	Stopped :	
CHLORPROMAZINE HYDROCHLORIDE (Other drug)	Reason :		
Batch :	Started :	Stopped :	
OMEPRAZOLE (Other drug)	Reason :		
Batch :	Started :	Stopped :	
SODIUM VALPROATE (Other drug)	Reason : Unspecified psychosis		
	2.2 Gram	Daily	
Batch :	Started : 01/10/2007	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				The patient was noted to a clozapine level of 660.
Haemoglobin				HB 107

Case Number : 237507

Data Entry Date : 04/02/2008
Hospitalisation : Admitted to hospital
Onset Date : 20/12/2007
Outcome : 02/01/2008
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 27/03/1974
Causality : Causality possible

Information: Ref number 18147 linked with 19398.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation	Patient was noted as having an increase in creatine phosphokinase levels. He also developed GI disturbances and a fever, up to 39.8 degrees celsius. He also developed orthostatic hypotension.	Ceased treatment with Clopine.
Gastrointestinal disorder	Caused or prolonged inpatient hospitalisation		
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 11/12/2007	S TERM	Stopped : 24/12/2007

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine kinase MB				01 Dec 2007: up to 18000

Case Number : 237510

Data Entry Date : 04/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 112

Onset Date : 08/10/2007

Age :

DOB : 10/01/1973

Outcome : 12/11/2007

Causality : Causality possible

Recovered

Information: A smoker and has a history of alcohol abuse. Patient's mother had a myocardial infarction aged 50.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased treatment with Clopine due to myocarditis.	Cessation of Clopine.
Chest pain			
Dyspnoea			
Ejection fraction decreased			

Medicine details :

CLOPINE (Suspected)	Reason : Schizo-affective type psychos
Tablet	250 Milligram Daily Oral
Batch :	Started : 20/09/2007 Stopped : 09/10/2007 0
RISPERIDONE (Other drug)	Reason :
	4 Milligram
Batch :	Started : Stopped :
SERTRALINE HYDROCHLORIDE (Other drug)	Reason :
	50 Milligram
Batch :	Started : Stopped :
SODIUM VALPROATE (Other drug)	Reason :
	750 Milligram
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Ejection fraction		08/10/2007	72%	
Ejection fraction		15/10/2007	47%	
Ejection fraction		15/12/2007	67%	

Public Case Detail

Cases Count: 393

Case Number : 237543

Data Entry Date : 04/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Retrograde ejaculation		The reporter informed that the patient developed retrograde ejaculation during therapy with Clozaril.	

Medicine details :

CLOZARIL (Suspected)	Reason :	
Batch :	Started :	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Prolactin				Normal result

Public Case Detail

Cases Count: 393

Case Number : 237560

Data Entry Date : 04/02/2008
Hospitalisation : Admitted to hospital
Onset Date : 02/01/2008
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 55
Age :
DOB : 23/08/1967
Causality : Causality possible

Information: The patient has had a poor response to many antipsychotics and has tardive dyskinesia (details not provided). No other relevant medical history, if any, was reported.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Life threatening	Severe neutropenia and severe leucopenia.	Clopine ceased.
Leukopenia	Life threatening		
Pharyngitis	Life threatening		

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 11/03/2004	L TERM	Stopped : 02/01/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		04/01/2008	0.60	X10^9/L
White blood cells		03/01/2008	0.50	X10^9/L
White blood cells		02/01/2008	0.50	X10^9/L
White blood cells		03/12/2007	5.30	X10^9/L
Neutrophils		04/01/2008	0.00	(X10^9/L)
Neutrophils		03/01/2008	0.00	(X10^9/L)
Neutrophils		02/01/2008	0.00	(X10^9/L)
Neutrophils		03/12/2007	3.30	(X10^9/L)
Serum drug level	(MG/DAY)	04/01/2008	0.0	Clozapine
Serum drug level	(MG/DAY)	03/01/2008	0.0	Clozapine
Serum drug level	(MG/DAY)	02/01/2008	0.0	Clozapine
Serum drug level	(MG/DAY)	03/12/2007	400.0	Clozapine

Public Case Detail

Cases Count: 393

Case Number : 237561

Data Entry Date : 04/02/2008

Hospitalisation :

Onset Date : 15/12/2007

Outcome :
Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 23/10/1967

Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Troponin increased	Life threatening	Patient experienced increased troponin whilst on Clopine treatment.	Clopine ceased.

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	275 Milligram	Daily	Oral
Batch :	Started : 06/12/2007	Stopped : 24/12/2007	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin				Dec 2007: 0.38 (Elevated)

Public Case Detail

Cases Count: 393

Case Number : 237565

Data Entry Date : 04/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/01/2008

Age :

DOB : 21/05/1952

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Life threatening	Patient's routine blood tests revealed severe neutropenia (grade 4) and severe leucopenia (grade 3).	Ceased Clopine.
Agranulocytosis	Life threatening		

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	100 Milligram Daily Oral
Batch :	Started : 22/11/2007 S TERM Stopped : 15/01/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		16/01/2008	1.90	(x10 ⁹ /L)
White blood cells		15/01/2008	1.80	(x10 ⁹ /L)
White blood cells		08/01/2008	4.60	(x10 ⁹ /L)
Neutrophils		16/01/2008	0.10	(X10 ⁹ /L)
Neutrophils		15/01/2008	0.10	(X10 ⁹ /L)
Neutrophils		08/01/2008	3.30	(X10 ⁹ /L)
Serum drug level		16/01/2008	0.0	Dose (MG)
Serum drug level		15/01/2008	0.0	Dose (MG)
Serum drug level		08/01/2008	100.0	Dose (MG)

Public Case Detail

Cases Count: 393

Case Number : 237576

Data Entry Date : 05/02/2008
Hospitalisation : Admitted to hospital
Onset Date : 05/11/2007
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age : 41Y
DOB :
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation	Patient stable on Clozapine but had multiple seizures. These are now thought to coincide with his attempts to quit smoking (reduced from 40 to 20 /day).	Clozapine withheld.
Convulsion	Caused or prolonged inpatient hospitalisation		

Medicine details :			
Cigarettes (Interaction)		Reason :	
Batch :	Started :	L TERM	Stopped : 0
CLOZARIL (Interaction)		Reason :	
Tablet	750 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped : 0
DITROPAN (Other drug)		Reason :	
	10 Milligram	Daily	Oral
Batch :	Started :		Stopped :
TOFRANIL (Other drug)		Reason :	
	25 Milligram	Daily	
Batch :	Started :		Stopped :
VALPRO (Other drug)		Reason :	
Tablet	2 Gram	Daily	Oral
Batch :	Started :		Stopped :

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Serum drug level				On admission, clozapine level was 1800.

Public Case Detail

Cases Count: 393

Case Number : 237577

Data Entry Date : 05/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 09/05/1976

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Possible myocarditis, pericardial effusion and tachycardia.	
Pericardial effusion			
Tachycardia			

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 21/02/2007	Stopped : 14/01/2008	0

Case Number : 237793

Data Entry Date : 11/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/04/2005

Age :

DOB : 03/10/1980

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Low neutrophil count and white blood cell count.	Cessation of Clozaril.
Antipsychotic drug level increased			
Neutrophil count decreased			

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	475 Milligram	Daily	Oral
Batch :	Started : 27/08/2003	Stopped : 08/06/2005	
EPILIM (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		01/12/2004	3.70	8.10x10 ⁹ /L pre-treatment
White blood cells		03/06/2005	3.40	8.10x10 ⁹ /L pre-treatment
White blood cells		05/07/2005	6.20	8.10x10 ⁹ /L pre-treatment
Neutrophils		01/12/2004	2.10	5.80x10 ⁹ /L pre treatment
Neutrophils		03/06/2005	1.30	5.80x10 ⁹ /L pre treatment
Neutrophils		05/07/2005	3.30	5.80x10 ⁹ /L pre treatment
Other data		29/04/2005	1080 mcg/L	Serum clozapine
Other data		09/06/2005	50 mcg/L	Serum clozapine

Public Case Detail

Cases Count: 393

Case Number : 237798

Data Entry Date : 11/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 15/06/1981

Outcome :

Causality : Causality possible

Unknown

Information: Medical History: Alcoholism/ drug abuser. The nurse informed that stutter started as soon as the patient was stated on Clozaril and patient's family had verified he did not have stutter before Clozaril.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dysphemia		Patient experienced stutter and twitch on his face, as well as weight gain.	
Facial spasm			
Weight increased			

Medicine details :

CLOZARIL (Suspected)

Reason :

Tablet

500 Milligram

Daily

Oral

Batch :

Started : 17/07/2006

Stopped :

Case Number : 237799

Data Entry Date : 11/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 31/07/1977

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular hypokinesia		A "recent" echocardiography showed that the patient's inferoseptum and inferior wall were mildly hypokinetic. The echocardiography also showed mild septal hypertrophy and right ventricular dilatation.	Metoprolol.
Dilatation ventricular			
Echocardiogram abnormal			
Hypertension			
Tachycardia			
Type 2 diabetes mellitus			
Ventricular hypertrophy			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	500 Milligram Daily Oral
Batch :	Started : 19/09/2005 Stopped :
CITALOPRAM HYDROBROMIDE (Other drug)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 237807

Data Entry Date : 11/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/01/2008

Age :

DOB : 19/11/1977

Outcome :

Causality : Causality possible

Unknown

Information: the physician advised that the patient had always had a low neutrophil count even before starting Clozaril, these levels fluctuated over the first 12 months.

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient's blood tests showed low neutrophil and white blood cell count.	Ceased Clozaril.
Neutrophil count decreased			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	450 Milligram	Daily	Oral
Batch :	Started : 11/01/2007	Stopped : 17/01/2008	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		17/01/2008	3.7	Pretreatment 5.9
White blood cells		07/02/2008	4.1	Pretreatment 5.9
Neutrophils		17/01/2008	1.4	pre-treatment 3.5
Neutrophils		07/02/2008	1.9	pre-treatment 3.5

Case Number : 237841

Data Entry Date : 12/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/01/2008

Age :

DOB : 10/09/1982

Outcome :

Causality : Causality probable

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Agranulocytosis	Ceased Clozaril

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	300 Milligram Daily Oral
Batch :	Started : 04/12/2007 Stopped : 21/01/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	24/11/2007	5.8	
White blood cells	(4.5-11.0)	04/12/2007	5.80	
White blood cells	(4.5-11.0)	14/01/2008	3.90	
White blood cells	(4.5-11.0)	21/01/2008	2.10	
White blood cells	(4.5-11.0)	22/01/2008	2.00	
White blood cells	(4.5-11.0)	23/01/2008	2.90	
Neutrophils	(1.8-7.7)	24/11/2007	3.23	
Neutrophils	(1.8-7.7)	04/12/2007	3.23	
Neutrophils	(1.8-7.7)	14/01/2008	2.30	
Neutrophils	(1.8-7.7)	21/01/2008	0.63	
Neutrophils	(1.8-7.7)	22/01/2008	0.30	
Neutrophils	(1.8-7.7)	23/01/2008	0.009	

Public Case Detail

Cases Count: 393

Case Number : 237842

Data Entry Date : 12/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/01/2008

Age :

DOB : 04/08/1957

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Deep vein thrombosis	Caused or prolonged inpatient hospitalisation	Patient developed deep vein thrombosis.	

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	750 Milligram	Daily	Oral
Batch :	Started : 17/05/1993	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Ultrasound				DVT confirmed at hospital by ultrasound.

Public Case Detail

Cases Count: 393

Case Number : 237846

Data Entry Date : 12/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/01/2008

Age :

DOB : 23/03/1951

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced decreased White blood cell count.	Clozaril was discontinued.
White blood cell count decreased			

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 01/06/1997	Stopped : 18/01/2008	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		18/01/2008	2.30	
White blood cells		18/02/2008	4.3	
Neutrophils		18/01/2008	1.10	
Neutrophils		18/02/2008	2.6	

Public Case Detail

Cases Count: 393

Case Number : 237994

Data Entry Date : 18/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 03/01/1956

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Cardiac complications.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 20/12/2006	Stopped :	

Case Number : 238008

Data Entry Date : 18/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age : 37Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction	Caused or prolonged inpatient hospitalisation	LV dysfunction (on TTE), LV wall thickened and reduction in ejection traction.	
Cardiac hypertrophy	Caused or prolonged inpatient hospitalisation		
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
Batch :	Started : Stopped :
ATROPINE (Other drug)	Reason :
	3 Dose Unspec Oral
Batch :	Started : Stopped :
COGENTIN (Other drug)	Reason :
	0.5 Milligram
Batch :	Started : Stopped :
DIAZEPAM (Other drug)	Reason :
	2 Milligram
Batch :	Started : Stopped :
Microgynon 50 ED (Other drug)	Reason :
	1
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				gated blood pool: EF 54%

Case Number : 238102

Data Entry Date : 20/02/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 15/01/2008

Age :

DOB : 22/04/1953

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Patient commenced on Clozaril on the 16/12/07 and on the 29/01/08, the patient's blood test results showed decreased white blood cells and neutrophils counts. Patient was afebrile and developed neutropenic fever, without clear source of infection.	Clozaril ceased the same day. Patient switched to aripiprazole on 01/02/08. Treated with IV tazocin and Granulocyte Colony Stimulating Factor (GCSF).
Anaemia	Caused or prolonged inpatient hospitalisation		
Febrile neutropenia	Caused or prolonged inpatient hospitalisation		
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	350 Milligram Daily Oral
Batch :	Started : 16/12/2007 Stopped : 29/01/2008
EFEXOR (Other drug)	Reason :
Tablet	Oral
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 ⁹ /L)	29/01/2008	1.90	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	30/01/2008	0.90	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	31/01/2008	0.70	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	02/02/2008	1.30	Pre treatment WBC = 9.2x10 ⁹ /L

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 ⁹ /L)	04/02/2008	0.70	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	05/02/2008	0.90	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	07/02/2008	1.50	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	08/02/2008	0.90	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	09/02/2008	0.80	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	10/02/2008	1.20	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	11/02/2008	4.00	Pre treatment WBC = 9.2x10 ⁹ /L
White blood cells	(4.5-11.0x10 ⁹ /L)	26/02/2008	7.4	Pre treatment WBC = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	29/01/2008	1.10	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	30/01/2008	0.40	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	31/01/2008	0.00	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	02/02/2008	0.10	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	04/02/2008	0.00	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	05/02/2008	0.00	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	07/02/2008	0.00	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	08/02/2008	0.00	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	09/02/2008	0.00	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	10/02/2008	0.10	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	11/02/2008	2.40	Pre treatment neut count = 9.2x10 ⁹ /L
Neutrophils	(1.8-7.7x10 ⁹ /L)	26/02/2008	5.0	Pre treatment neut count = 9.2x10 ⁹ /L
Haemoglobin		26/02/2008	107	Hb = 112 (mild anaemia).

Public Case Detail

Cases Count: 393

Case Number : 238113

Data Entry Date : 20/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 31/05/1966

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Pateint experienced possible cardiomyopathy and dilated left ventricle whilst being treated with Clopine.	
Dilatation ventricular			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	600 Milligram Daily Oral
Batch :	Started : 24/05/2006 Stopped :

Case Number : 238132

Data Entry Date : 20/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 43

Onset Date : 17/12/2007

Age :

DOB : 28/02/1952

Outcome :

Causality : Causality possible

Not yet recovered

Information: Patient has a 6 year history of schizophrenia.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Eosinophilia. Patient began experiencing a fever which was described as severe in intensity. Patient was also suffering from urinary incontinence and a headache and had raised inflammatory markers (white blood cell count, neutrophils and C-reactive protien).	Clopine ceased.
Headache			
Pyrexia			
Urinary incontinence			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 05/12/2007	Stopped : 04/01/2008	

Public Case Detail

Cases Count: 393

Case Number : 238272

Data Entry Date : 25/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/12/2007

Age :

DOB : 11/06/1949

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Afer 5 years starting Clozaril, the patient had a significant rise in creatine kinase levels.	Clozaril was discontinued.
Myopathy			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 21/01/2003	Stopped : 20/12/2007	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin				The patient's troponin were normal.
Creatine phosphokinase		20/12/2007	3743	

Public Case Detail

Cases Count: 393

Case Number : 238290

Data Entry Date : 26/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/01/2008

Age :

DOB : 29/09/1981

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Salivary gland enlargement		Patient experienced salivary gland swelling.	Antibiotics and Ibruprofen.

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	625 Milligram	Daily	Oral
Batch :	Started : 07/03/2006	Stopped :	
RISPERDAL (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 238291

Data Entry Date : 26/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/01/2008

Age :

DOB : 10/10/1980

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Diarrhoea		Patient experienced eosinophil count increased, white blood count increased, neutrophil count increased, and symptoms of diarrhoea.	
Eosinophilia			
Neutrophil count increased			
White blood cell count increased			

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 07/01/2008	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 238347

Data Entry Date : 27/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/08/2003

Age :

DOB : 01/05/1984

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Palpitations		The patient developed sinus tachycardia in Aug 2003 approximately 8 weeks after commencing Clozaril.	Clozaril discontinued
Electrocardiogram QT prolonged			
Sinus tachycardia			

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 19/06/2003	Stopped :	30/12/2007
BENZTROPINE MESYLATE (Other drug)		Reason :	
Tablet	2 Milligram		Oral
Batch :	Started :	Stopped :	
MIRTAZAPINE (Other drug)		Reason :	
Tablet			
Batch :	Started :	Stopped :	
SODIUM VALPROATE (Other drug)		Reason :	
Tablet			
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Heart Rate				120 - 140 beats per minute for the last week

Public Case Detail

Cases Count: 393

Case Number : 238358

Data Entry Date : 27/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/02/2008

Age :

DOB : 27/03/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis		Patient developed diabetic ketoacidosis. Agranulocytosis.	Remain off Clozaril
Neutrophil count decreased			
White blood cell count decreased			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 03/12/2007	Stopped : 05/02/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	03/12/2007	5.80	
White blood cells	(4.5-11.0)	05/02/2008	2.40	
Neutrophils	(18-7.7)	03/12/2007	4.00	
Neutrophils	(18-7.7)	05/02/2008	1.20	

Case Number : 238427

Data Entry Date : 29/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/02/2008

Age :

DOB : 17/11/1964

Outcome :

Causality : Causality probable

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Caused or prolonged inpatient hospitalisation	During routine blood examinations it was revealed that the patient had severe neutropenia and leucopenia (assessed as life threatening and severe). This was described as marked neutropenia secondary to clozapine treatment.	Clopine was ceased.
Agranulocytosis	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia		
Tablet	500 Milligram	Daily	Oral	
Batch :	Started : 17/12/2007	Stopped : 05/02/2008		
DIAZEPAM (Other drug)		Reason : Anxiety neurosis		
Tablet	5 Milligram	As necessary	Oral	
Batch :	Started :	Stopped :		
LITHIUM CARBONATE (Other drug)		Reason :		
Tablet	900 Milligram		Oral	
Batch :	Started :	Stopped :		
MIRTAZAPINE (Other drug)		Reason : Depression		
Tablet	30 Milligram	Daily	Oral	
Batch :	Started :	Stopped :		

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		29/01/2008	7.40	
White blood cells		05/02/2008	2.00	
White blood cells		06/02/2008	1.60	
Neutrophils		29/01/2008	5.30	
Neutrophils		05/02/2008	0.01	
Neutrophils		06/02/2008	0.03	

Public Case Detail

Cases Count: 393

Case Number : 238456

Data Entry Date : 29/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/07/1948

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Patient experienced agranulocytosis-progressive neutropenia and fever.	IV antibiotics and GCSF.
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine details :	
CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Batch :	Started : 29/10/2007 Stopped :

Case Number : 238551

Data Entry Date : 04/03/2008

Hospitalisation : Admitted to hospital

Onset Date :

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age :

DOB : 06/12/1960

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient experienced weight gain and hepatitis.	Clopine ceased.
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	50 Milligram Daily Oral
Batch :	Started : 04/01/2008 Stopped : 04/01/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				White blood cell count and neutrophil counts normal.

Public Case Detail

Cases Count: 393

Case Number : 238583

Data Entry Date : 04/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/02/2008

Age :

Outcome : 09/02/2008

DOB : 04/02/1961

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis which manifested as generalised flu-like illness and fatigue.	Ceased Clopine
Troponin I increased			

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 25/01/2008	Stopped : 08/02/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin		06/02/2008	0.10	baseline <0.05
Troponin		08/02/2008	0.09	baseline <0.05

Public Case Detail

Cases Count: 393

Case Number : 238805

Data Entry Date : 11/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/10/2007

Age :

DOB : 14/02/1957

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	275 Milligram	Daily	Oral
Batch :	Started : 27/08/2007	Stopped : 30/10/2007	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				10/2007: Abnormal cardiomyopathy.

Public Case Detail

Cases Count: 393

Case Number : 238872

Data Entry Date : 12/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 06/02/2008

Age :

DOB : 30/07/1969

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	Clozaril discontinued.

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 22/01/2008	Stopped :	06/02/2008

Public Case Detail

Cases Count: 393

Case Number : 238873

Data Entry Date : 12/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 13/02/2008

Age :

DOB : 27/08/1963

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	125 Milligram	Daily	Oral
Batch :	Started : 31/01/2008	Stopped :	14/02/2008

Case Number : 238905

Data Entry Date : 13/03/2008

Gender : M

Hospitalisation : Required a specialist consultation

Weight (kg) : 0

Onset Date :

Age :

DOB : 02/06/1975

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The suspected myocarditis presented as chest pain, tachycardia, fever of (38c), elevated troponin, elevated creatine kinase (CK) and elevated C- reactive protein (CRP). The patient was symptomatic and was unwell.	Clopine ceased.
Blood creatine phosphokinase increased			
C-reactive protein increased			
Chest pain			
Pyrexia			
Tachycardia			
Troponin increased			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	100 Milligram Daily Oral
Batch :	Started : 11/02/2008 Stopped : 19/02/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				An electrocardiogram was completed revealing subtle changes. Not specified.

Public Case Detail

Cases Count: 393

Case Number : 238907

Data Entry Date : 13/03/2008
Hospitalisation : Admitted to hospital
Onset Date : 15/01/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 19/11/1973
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Dystonia	Caused or prolonged inpatient hospitalisation	Acute muscle dystonia; spasm lasted for a few minutes then ceased then restarted, all day, becoming worse. The spasms affected his face, mouth and limbs and was distressing for him.	Treated with Cogentin.
Muscle spasms	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	75 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 238936

Data Entry Date : 13/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 27/12/2007

Age :

DOB : 25/09/1958

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Treatment was discontinued on 27 Dec 2007 due to the onset of diabetes, lack of efficacy, patient's objection to regular blood tests and weight gain. On unspecified dates the patient experienced panic attacks, paranoid ideation with ego dystonic (almost delusion) ideation in spite of treatment with Clozapine and Aropax (paroxetine hydrochloride) and Valproate.	Clozaril treatment was discontinued.
Delusion			
Drug ineffective			
Panic attack			
Paranoia			
Weight increased			

Medicine details :

AROPAX (Suspected)	Reason :
Batch :	Started : Stopped :
CLOZARIL (Suspected)	Reason :
Tablet	Oral
Batch :	Started : 27/06/1994 Stopped : 27/12/2007
VALPRO (Suspected)	Reason :
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 239132

Data Entry Date : 19/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 09/08/1964

Unknown

Causality : Causality probable

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		43 year old patient who ceased treatment with Clopine due to neutropenia, leucopenia and agranulocytosis.	Clopine was ceased on 26 Feb 2008 as a result of the events.
Leukopenia			
Neutropenia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	350 Milligram Daily Oral
Batch :	Started : 15/10/2005 Stopped : 26/02/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		29/02/2008	3.30	(x 10 ⁹ L)
White blood cells		28/02/2008	3.10	(x 10 ⁹ L)
White blood cells		27/02/2008	4.30	(x 10 ⁹ L)
White blood cells		26/02/2008	2.20	(x 10 ⁹ L)
White blood cells		22/02/2008	3.70	(x 10 ⁹ L)
White blood cells		20/02/2008	3.30	(x 10 ⁹ L)
White blood cells		15/02/2008	3.90	(x 10 ⁹ L)
Neutrophils		29/02/2008	1.10	(x 10 ⁹ L)
Neutrophils		28/02/2008	1.30	(x 10 ⁹ L)
Neutrophils		27/02/2008	2.90	(x 10 ⁹ L)
Neutrophils		26/02/2008	0.80	(x 10 ⁹ L)
Neutrophils		22/02/2008	1.90	(x 10 ⁹ L)
Neutrophils		20/02/2008	1.50	(x 10 ⁹ L)
Neutrophils		15/02/2008	2.20	(x 10 ⁹ L)
Serum drug level		29/02/2008	0.0	Clopine
Serum drug level		28/02/2008	0.0	Clopine
Serum drug level		27/02/2008	0.0	Clopine
Serum drug level		26/02/2008	0.0	Clopine

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		22/02/2008	350.0	Clopine
Serum drug level		20/02/2008	350.0	Clopine
Serum drug level		15/02/2008	350.0	Clopine

Case Number : 239147

Data Entry Date : 20/03/2008
Hospitalisation : Admitted to hospital
Onset Date : 19/02/2008
Outcome : 22/02/2008
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 11/08/1978
Causality : Causality certain

Information: Cert (L.D.)

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug toxicity	Caused or prolonged inpatient hospitalisation	A 29 year old male who ceased treatment with Clopine due to tachycardia.	Clopine was ceased and the patient was admitted to hospital and monitored for 4 days.
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected) Reason :
 Tablet 450 Milligram Daily Oral
Batch : **Started :** 01/02/2008 **Stopped :** 19/02/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				The patient's white blood cell and neutrophil counts were within normal limits for the treatment period.
Neutrophils				The patient's white blood cell and neutrophil counts were within normal limits for the treatment period.
Other data				Blood clozapine levels (date unknown) - Increased

Public Case Detail

Cases Count: 393

Case Number : 239233

Data Entry Date : 26/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/02/2008

Age :

Outcome : 22/02/2008

DOB : 19/10/1961

Death

Causality : Causality possible

Information: FI provides additional patient history but cause of death still not yet available

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	46 year old male patient died due to unknown reasons whilst being treated with Clopine.	

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 23/01/2007	L TERM	Stopped :

Case Number : 239266

Data Entry Date : 26/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 60

Onset Date : 03/03/2008

Age :

Outcome :

DOB : 12/09/1945

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis	Normal saline, anginine SL
Chest pain	Caused or prolonged inpatient hospitalisation		
Hypokinesia	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	175 Milligram Daily Oral
Batch :	Started : 19/02/2008 Stopped : 04/03/2008
EPILIM (Other drug)	Reason :
	1.2 Gram Daily
Batch :	Started : Stopped :
SOLIAN (Other drug)	Reason :
	300 Milligram Daily
Batch :	Started : Stopped :
TEMAZEPAM (Other drug)	Reason :
	20 Milligram As necessary
Batch :	Started : Stopped :
TRIMETHOPRIM (Other drug)	Reason :
	300 Milligram Daily
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Myocarditis confirmed with echocardiogram. Echo on 07/03 showed normal cavity size and wall thickness of LV but mildly impaired contraction with diffuse hypokinesia. EF is 48% troponin was 0.04 microg/l on 05/03 and 0.01 on 06/03, oesinophil 0.3 on 05/03, 0.2 on 06/03, 0.5 on 10/03.

Public Case Detail

Cases Count: 393

Case Number : 239308

Data Entry Date : 27/03/2008
Hospitalisation : Admitted to hospital
Onset Date : 18/04/2007
Outcome :
 Recovered

Gender : F
Weight (kg) : 0
Age : 33Y
DOB :
Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia	Clozapine ceased.

Medicine details :	
CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia
Batch :	Started : 26/03/2007 Stopped : 18/04/2007

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		19/04/2007	5.1	
Neutrophils		19/04/2007	1.9	
Neutrophils		21/04/2007	6.1	

Public Case Detail

Cases Count: 393

Case Number : 239365

Data Entry Date : 31/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 24/11/1951

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizure and/or increase seizures.	Clozaril was discontinued.

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	112.5 Milligram	Daily	Oral
Batch :	Started : 02/03/1998	Stopped : 03/03/2008	

Case Number : 239377

Data Entry Date : 31/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 72

Onset Date : 06/02/2008

Age :

DOB : 08/01/1937

Outcome : 25/02/2008

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Life threatening	Decreased liver function	Clozapine ceased

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified psychosis	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 19/06/2007	Stopped : 08/02/2008	
LITHIUM CARBONATE (Other drug)		Reason : Prophylaxis	
Tablet	1 Gram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
SAP = ALP		06/02/2008	684	
GGT = SGGT = GGTP		06/02/2008	346	
ALT = SGPT		06/02/2008	344	
AST = SGOT		06/02/2008	245	
Bilirubin		06/02/2008	Normal	

Public Case Detail

Cases Count: 393

Case Number : 239379

Data Entry Date : 31/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 23/02/2008

Age :

DOB : 14/10/1944

Outcome : 23/02/2008

Causality : Causality possible

Death

Information: FI indictates death possibly due to cardiac arrhythmia but coroner's report not yet available

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death	

Medicine details :

CLOZAPINE (Suspected)

Reason :

Tablet

300 Milligram

Daily

Oral

Batch :

Started : 29/11/2006

Stopped : 23/02/2008

Public Case Detail

Cases Count: 393

Case Number : 239389

Data Entry Date : 31/03/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 18/05/1962

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Rapid heart beat, drooling and tingling of the arms and legs.	
Drooling			
Heart rate increased			
Salivary hypersecretion			

Medicine details :			
CLOZARIL (Suspected)		Reason :	
			Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 239438

Data Entry Date : 01/04/2008
Hospitalisation : Admitted to hospital
Onset Date : 12/03/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 28/12/1986
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Seizure.	

Medicine details :			
CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 19/12/2007	Stopped :	Ongoing.
EPILIM (Other drug)	Reason :		
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 239439

Data Entry Date : 01/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 02/03/2008

Age :

DOB : 09/07/1986

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizure.	

Medicine details :

CLOZARIL (Suspected)	Reason :	
Tablet	125 Milligram Daily	Oral
Batch :	Started :	Stopped : 21/02/2002

Case Number : 239457

Data Entry Date : 01/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/12/2007

Age :

DOB : 28/04/1942

Outcome : 15/03/2008

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced severe leucopenia and neutropenia.	Clopine ceased.
Neutropenia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	225 Milligram Daily Oral
Batch :	Started : 24/02/2004 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		17/12/2007	2.80	WCC (x10 ⁹ /L)
White blood cells		22/11/2007	5.20	WCC (x10 ⁹ /L)
White blood cells		16/03/2008	3.90	WCC (x10 ⁹ /L)
White blood cells		15/03/2008	3.40	WCC (x10 ⁹ /L)
White blood cells		14/03/2008	2.60	WCC (x10 ⁹ /L)
White blood cells		13/03/2008	1.30	WCC (x10 ⁹ /L)
White blood cells		12/03/2008	1.90	WCC (x10 ⁹ /L)
White blood cells		10/03/2008	2.20	WCC (x10 ⁹ /L)
White blood cells		11/02/2008	5.30	WCC (x10 ⁹ /L)
White blood cells		15/01/2008	3.70	WCC (x10 ⁹ /L)
White blood cells		08/01/2008	3.80	WCC (x10 ⁹ /L)
White blood cells		02/01/2008	3.30	WCC (x10 ⁹ /L)
White blood cells		17/12/2007	2.80	WCC (x10 ⁹ /L)
White blood cells		22/11/2007	5.20	WCC (x10 ⁹ /L)
Neutrophils		17/12/2007	2.10	NC (x10 ⁹ /L)
Neutrophils		22/11/2007	4.30	NC (x10 ⁹ /L)
Neutrophils		16/03/2008	2.20	NC (x10 ⁹ /L)
Neutrophils		15/03/2008	2.20	NC (x10 ⁹ /L)
Neutrophils		14/03/2008	1.40	NC (x10 ⁹ /L)
Neutrophils		13/03/2008	0.60	NC (x10 ⁹ /L)
Neutrophils		12/03/2008	1.20	NC (x10 ⁹ /L)

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		10/03/2008	1.50	NC (x10 ⁹ /L)
Neutrophils		11/02/2008	4.30	NC (x10 ⁹ /L)
Neutrophils		15/01/2008	2.80	NC (x10 ⁹ /L)
Neutrophils		08/01/2008	2.90	NC (x10 ⁹ /L)
Neutrophils		02/01/2008	2.20	NC (x10 ⁹ /L)
Neutrophils		17/12/2007	2.10	NC (x10 ⁹ /L)
Neutrophils		22/11/2007	4.30	NC (x10 ⁹ /L)
Other data		17/12/2007	225.0	Dose (MG)
Other data		22/11/2007	225.0	Dose (MG)
Other data		16/03/2008	0.0	Dose (MG)
Other data		15/03/2008	0.0	Dose (MG)
Other data		14/03/2008	0.0	Dose (MG)
Other data		13/03/2008	0.0	Dose (MG)
Other data		12/03/2008	225.0	Dose (MG)
Other data		10/03/2008	225.0	Dose (MG)
Other data		11/02/2008	225.0	Dose (MG)
Other data		15/01/2008	225.0	Dose (MG)
Other data		08/01/2008	225.0	Dose (MG)
Other data		02/01/2008	225.0	Dose (MG)
Other data		17/12/2007	225.0	Dose (MG)
Other data		22/11/2007	225.0	Dose (MG)

Public Case Detail

Cases Count: 393

Case Number : 239475

Data Entry Date : 02/04/2008
Hospitalisation : Admitted to hospital
Onset Date : 12/03/2008
Outcome : 07/04/2008
 Death, maybe drug

Gender : F
Weight (kg) : 0
Age :
DOB : 24/04/1980
Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Leukopenia	Death	Patient experienced neutropenia and leucopenia whilst on treatment with Clopine.	Clopine ceased. ICU.
Agranulocytosis	Life threatening		
Infection	Life threatening		
Neutropenia	Life threatening		

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 26/01/2008	Stopped : 12/03/2008	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		05/03/2008	8.10	Unknown date: 1.00. Dose 350.0
Neutrophils		05/03/2008	6.10	Date unknown: 0.00. Dose 350.0
Serum drug level		05/03/2008	350.0	Clopine Unknown date = 350.0mg 05/03/08 = 350.0mg

Public Case Detail

Cases Count: 393

Case Number : 239494

Data Entry Date : 02/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/12/1944

Outcome :

Causality : Causality possible

Death

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Death	Patient died from a pulmonary embolism secondary to a deep vein thrombosis whilst being treated with Clopine.	
Deep vein thrombosis	Death		

Medicine details :

CLOPINE (Suspected)	Reason :
	300 Milligram Daily
Batch :	Started : 04/10/2006 L TERM Stopped :

Public Case Detail

Cases Count: 393

Case Number : 239564

Data Entry Date : 03/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/02/2008

Age :

DOB : 03/06/1976

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased treatment with Clopine due to myocarditis.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 12/02/2008	Stopped : 28/02/2008	

Public Case Detail

Cases Count: 393

Case Number : 239586

Data Entry Date : 04/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/07/1980

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased clozapine

Medicine details :			
CLOZAPINE (Suspected)	Reason :		
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 27/02/2008	Stopped : 13/03/2008	

Case Number : 239693

Data Entry Date : 08/04/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 87

Onset Date : 06/02/2008

Age :

DOB : 04/10/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Patient experienced a relapse of his psychosis characterised by paranoia and severe thought disorder in the context of Clozaril non-compliance and was admitted to hospital. Clozaril was recommenced and increased to 450mg. On the higher dose the patient began to show some improvement in his mental state. On approximately 16 Feb 08 the patient developed a sinus tachycardia with a heart rate of about 120. A cardiac MRI performed on 18 Feb 08 showed moderate idiopathic cardiomyopathy but no evidence of active myocarditis.	Cardiology unit advised discontinuation of Clozaril.
Paranoia	Caused or prolonged inpatient hospitalisation		
Psychotic disorder	Caused or prolonged inpatient hospitalisation		
Sinus tachycardia	Caused or prolonged inpatient hospitalisation		
Thinking abnormal	Caused or prolonged inpatient hospitalisation		
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified psychosis
	450 Milligram Daily
Batch :	Started : 14/08/2007 Stopped : 0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		12/08/2007	9.51 x 10 ⁹ /L	
Neutrophils		12/08/2007	5.54 x 10 ⁹ /L	
Echocardiogram				26 Feb 08. Mild to moderately dilated Left Ventricle (LV) with mild to moderate systolic dysfunction. Mild Left Atrium (LA) dilation.
Magnetic Resonance Imaging				18 Feb 08. Cardiac MRI report showed moderate idiopathic cardiomyopathy but no evidence of active myocarditis.

Public Case Detail

Cases Count: 393

Case Number : 239738

Data Entry Date : 08/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 23/08/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient's weight increased significantly, about 50kg to 90kg in about 3-4 months and she had developed significant abdominal obesity.	
Central obesity			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	125 Milligram	Daily	Oral
Batch :	Started : 19/05/2003	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 239904

Data Entry Date : 14/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/02/2008

Age :

DOB : 05/12/1980

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased treatment with Clopine due to myocarditis. Temperature spike. Troponin increased.	Ceased Clopine
Electrocardiogram ST segment elevation			
Pyrexia			
Troponin increased			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 18/02/2008	Stopped : 29/02/2008	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		29/02/2008	0.14	
Heart Rate				? March 2008 Tachycardia
White blood cells		07/03/2008	13.60	
White blood cells		03/03/2008	12.10	
Neutrophils		07/03/2008	9.17	
Neutrophils		03/03/2008	7.22	
Serum drug level		07/03/2008	175.0	Clopine
Serum drug level		03/03/2008	175.0	Clopine
Electrocardiography				On 13 Mar 2008 patient developed ECG changes (ST elevation). A cardiologists investigation diagnosed the patient as having myocarditis and clozapine was ceased.

Case Number : 239907

Data Entry Date : 14/04/2008
Hospitalisation : Admitted to hospital
Onset Date : 13/05/2007
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 13/04/1969
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Lethargy	Caused or prolonged inpatient hospitalisation	Patient was transferred to hospital on the 13/5/07 due to a three day history of lethargy. The patient spiked a temperature of 39.4 degrees. He also had a productive cough and was tachycardic on admission. He was diagnosed as having pneumonia but his chest x-ray was clear.	Treated for pneumonia, IV penicillin for 3 days then amoxicillin.
Cough	Caused or prolonged inpatient hospitalisation		
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia
150 Milligram Daily	
Batch :	Started : 30/04/2007 Stopped :
LORAZEPAM (Other drug)	Reason :
1 Milligram	
Batch :	Started : Stopped :
RISPERIDONE (Other drug)	Reason :
Injection 37.5 Milligram	Intramuscular
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 239965

Data Entry Date : 15/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 12/05/1982

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Patient complained of urinary incontinence had become worse and gained 50 kg.	
Weight increased			

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	600 Milligram Daily Oral
Batch :	Started : 20/02/2006 Stopped :

Case Number : 239992

Data Entry Date : 15/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/03/2008

Age :

DOB : 08/09/1988

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		On 19 March 08 patient experienced a loss of consciousness and postural hypotension both described as moderate in severity. Electrocardiogram changes and dyslipidemia.	Clopine ceased.
Dyslipidaemia			
Electrocardiogram change			
Orthostatic hypotension			

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 18/03/2008	Stopped : 24/03/2008	
LITHIUM CARBONATE (Other drug)		Reason : Unspecified schizophrenia	
	1000 Milligram	Daily	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography		24/03/2008	Abnormal	
Triglyceride		24/03/2008	20.6	(Ref range <2.0)
Cholesterol		24/03/2008	7.8	(Ref range <5.5)

Public Case Detail

Cases Count: 393

Case Number : 240021

Data Entry Date : 15/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 27/03/2008

Age :

DOB : 17/07/1958

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and leucopenia.	Clopine ceased.
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	700 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		01/04/2008	3.10	WBC
White blood cells		31/03/2008	2.79	WBC
White blood cells		28/03/0200	3.40	WBC
White blood cells		27/03/2008	3.90	WBC
White blood cells		25/03/0200	3.70	WBC
White blood cells		25/02/0200	6.40	WBC
White blood cells		29/01/0200	6.60	WBC
Neutrophils		01/04/2008	1.49	NC
Neutrophils		31/03/2008	0.92	NC
Neutrophils		28/03/0200	1.86	NC
Neutrophils		27/03/2008	1.43	NC
Neutrophils		25/03/0200	1.41	NC
Neutrophils		25/02/0200	3.69	NC
Neutrophils		29/01/0200	3.63	NC
Other data		01/04/2008	700.0	Dose (MG/DAY).
Other data		31/03/2008	700.0	Dose (MG/DAY).
Other data		28/03/0200	700.0	Dose (MG/DAY).
Other data		27/03/2008	700.0	Dose (MG/DAY).

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data		25/03/0200	700.0	Dose (MG/DAY).
Other data		25/02/0200	700.0	Dose (MG/DAY).
Other data		29/01/0200	700.0	Dose (MG/DAY).

Public Case Detail

Cases Count: 393

Case Number : 240045

Data Entry Date : 16/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/03/2008

Age :

Outcome :

DOB : 13/10/1989

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient experienced pericardial efusion and left ventricular hypertrophy. Resting pulse was 90 to 110 beats per minutes.	Clopine was being reduced from 350mg by 50mg every 2 days to Zero.
Heart rate increased			
Left ventricular hypertrophy			

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 31/01/2008	Stopped :	
VENLAFAXINE HYDROCHLORIDE (Other drug)		Reason :	
Batch :	Started : 15/09/0207	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Echocardiogram which confirmed the mild pericardial effusion on 20/Mar/2008. Also identified borderline left ventricular hypertrophy.

Case Number : 240065

Data Entry Date : 16/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/08/1962

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed cardiomyopathy after his echocardiogram in Jan 2008, patient was initially on 700 mg and dose reduced to 350 mg then patient became psychotic.	
Mental impairment			
Psychotic disorder			
Treatment noncompliance			
Ventricular dysfunction			

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet 400 Milligram Daily	Oral
Batch :	Started : 03/03/2008 Stopped :
CLOZARIL (Suspected)	Reason :
Tablet 350 Milligram Daily	Oral
Batch :	Started : Stopped :
CLOZARIL (Suspected)	Reason :
Tablet 700 Milligram Daily	Oral
Batch :	Started : 01/10/2007 Stopped : 02/03/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Echocardiogram showed a decreased in left ventricular function.

Public Case Detail

Cases Count: 393

Case Number : 240067

Data Entry Date : 16/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 07/07/1983

Outcome :

Causality : Causality possible

Not yet recovered

Information: Clopine treatment was ceased on 29-Mar-2008. The patient was admitted to hospital and is currently in the intensive care unit (ICU).

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	Clopine was ceased and currently is in ICU.

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

650 Milligram

Daily

Oral

Batch :

Started : 26/02/2007

Stopped : 29/03/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				Normal
Neutrophils				Normal

Case Number : 240155

Data Entry Date : 18/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 134

Onset Date :

Age :

DOB : 19/06/1979

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Metabolic syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced metabolic syndrome, elevated alt,and GGT.	Clopine was swapped to amisulpride.
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	350 Milligram Daily Oral
Batch :	Started : 24/09/2004 Stopped :
AMITRIPTYLINE HYDROCHLORIDE (Other drug)	Reason :
Batch :	Started : Stopped :
ATORVASTATIN (Other drug)	Reason :
Batch :	Started : Stopped :
METFORMIN HYDROCHLORIDE (Other drug)	Reason :
Batch :	Started : Stopped :
PANTOPRAZOLE (Other drug)	Reason :
Batch :	Started : Stopped :
QUETIAPINE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Liver function tests				Elevated ALT and GGT to 5 times the normal level.

Public Case Detail

Cases Count: 393

Case Number : 240188

Data Entry Date : 21/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/01/2008

Age : 35Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Unable to ejaculate.	Aripiprazole and propranolol ceased.

Medicine details :			
Aripiprazole (Suspected)		Reason :	
Tablet	30 Milligram	Daily	Oral
Batch :	Started :	Stopped : 19/01/2008	
CLOZAPINE (Suspected)		Reason :	
	500 Milligram	Daily	
Batch :	Started :	Stopped :	
PROPRANOLOL HYDROCHLORIDE (Suspected)		Reason :	
	20 Milligram	Daily	
Batch :	Started :	Stopped : 18/01/2008	
VALPRO (Suspected)		Reason :	
Tablet	2.5 Gram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 240528

Data Entry Date : 01/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/01/2008

Age :

DOB : 01/07/1962

Outcome :

Causality : Causality possible

Unknown

Information: Possible hypersplenism.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and thrombocytopenia.	
Thrombocytopenia			

Medicine details :

CLOZARIL (Suspected)	Reason :		
Tablet			Oral
Batch :	Started : 22/04/2003	L TERM	Stopped :
CITALOPRAM HYDROBROMIDE (Other drug)	Reason :		
Batch :	Started :		Stopped :
COLOXYL (Other drug)	Reason :		
Batch :	Started :		Stopped :
HYOSCINE NOS (Other drug)	Reason :		
Batch :	Started :		Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Hepatitis C antibody				Chronic hepatitis C (liver function test abnormal).
Platelets				Platelet count abnormal.
White blood cells		03/12/2007	3.88	Date unknown WBC: 425
White blood cells		27/12/2007	3.21	Date unknown WBC: 425
White blood cells		21/01/2008	2.66	Date unknown WBC: 425
White blood cells		22/01/2008	3.13	Date unknown WBC: 425
Neutrophils		03/12/2007	1.90	Pre - 2003 Date unknown NC: 2.3 and 1.6
Neutrophils		27/12/2007	2.00	Pre - 2003 Date unknown NC: 2.3 and 1.6
Neutrophils		22/01/2008	1.8	Pre - 2003 Date unknown NC: 2.3 and 1.6

Case Number : 240564

Data Entry Date : 05/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/04/2008

Age :

DOB : 09/01/1985

Outcome :

Causality : Causality possible

Not yet recovered

Information: Clozapine on 01/07/03 and switched to Clopine on 13/09/04 and was taking Clopine 125 mg PO daily at the time of the event. The patient was on doses as high as 400 mg PO for th majority of her treatment, 3 years 29 weeks 4 days.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Bloated stomach, severe neutropenia and leucopenia.	Ceased Clopine 07/04/08
Abdominal distension	Life threatening		
Leukopenia	Life threatening		

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	125 Milligram	Daily	Oral
Batch :	Started : 13/09/2004	Stopped : 07/04/2008	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		04/04/2008	2.40	
White blood cells		29/02/2008	7.00	
White blood cells		05/02/2008	6.80	
White blood cells		07/01/2008	6.70	
White blood cells		30/12/2007	6.10	
White blood cells		05/11/2007	6.80	
White blood cells		08/10/2007	6.70	
White blood cells		06/09/2007	7.20	
White blood cells		16/08/2007	7.30	
White blood cells		19/07/2007	6.30	
Neutrophils		04/04/2008	0.30	
Neutrophils		29/02/2008	4.40	
Neutrophils		05/02/2008	4.30	
Neutrophils		07/01/2008	4.10	
Neutrophils		30/11/2007	3.80	
Neutrophils		05/11/2007	3.70	
Neutrophils		08/10/2007	4.40	
Neutrophils		06/09/2007	5.20	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		16/08/2007	5.90	
Neutrophils		19/07/2007	4.40	
Other data		04/04/2008	0.0	Dose of Clopine
Other data		29/02/2008	125.0	Dose of Clopine
Other data		05/02/2008	125.0	Dose of Clopine
Other data		07/01/2008	150.0	Dose of Clopine
Other data		30/12/2007	175.0	Dose of Clopine
Other data		05/11/2007	200.0	Dose of Clopine
Other data		08/10/2007	225.0	Dose of Clopine
Other data		06/09/2007	250.0	Dose of Clopine
Other data		16/08/2007	300.0	Dose of Clopine
Other data		19/07/2007	325.0	Dose of Clopine

Public Case Detail

Cases Count: 393

Case Number : 240573

Data Entry Date : 05/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/04/2008

Age :

DOB : 22/12/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myopericarditis		Patient experienced myopericarditis.	

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 19/03/2008	Stopped : 04/04/2008	

Case Number : 240650

Data Entry Date : 06/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 73Y

Outcome :

DOB :

Unknown

Causality : Causality probable

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome, nausea, vomiting, pyrexia.	Clozaril was ceased.
Nausea			
Pyrexia			
Vomiting			

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 27/03/2008	Stopped : 10/04/2008	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
GGT = SGGT = GGTP				GGT Increased. GGT elevated to 223.
C-Reactive Protein				CRP increased. CRP elevated to 35.

Public Case Detail

Cases Count: 393

Case Number : 240686

Data Entry Date : 07/05/2008
Hospitalisation : Admitted to hospital
Onset Date : 28/03/2007
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 22/03/1967
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient presented with weight gain and oversedation. Also recent diagnosis of non-insulin dependent diabetes mellitus was reported by the physician.	Clozaril was discontinued.
Sedation	Caused or prolonged inpatient hospitalisation		
Type 2 diabetes mellitus	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZAPINE (Suspected)			
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 27/10/2005	Stopped : 02/04/2008	0
ENDONE (Other drug)			
	5 Milligram		
Batch :	Started :	Stopped :	
PROLADONE (Other drug)			
	30 Milligram		
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 240752

Data Entry Date : 08/05/2008
Hospitalisation : Admitted to hospital
Onset Date : 27/03/2008
Outcome : 27/03/2008
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 15/02/1983
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation	Drug level increased.	Luvox discontinued. Clozapine withheld and re-introduced.

Medicine details :			
CLOPINE (Interaction)		Reason : Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 30/01/2007	Stopped :	0
LUVOX (Interaction)		Reason :	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 15/03/2008	Stopped : 27/03/2008	Discontinued.

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Serum drug level				Clozapine serum level increased to 2220.

Public Case Detail

Cases Count: 393

Case Number : 240832

Data Entry Date : 13/05/2008

Gender : U

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/04/2008

Age :

DOB : 22/12/1982

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis, pyrexia, dizziness, chest pain, hyperhidrosis, hypotension, Troponin increased.	Clozaril ceased.
Cardiac enzymes increased			
Chest pain			
Dizziness			
Electrocardiogram abnormal			
Hyperhidrosis			
Hypotension			
Pyrexia			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 01/04/2008	Stopped : 10/04/2008	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin	>0.04	18/04/2008	0.29	Unknown dates troponin was 0.16 and 0.06.
Troponin	>0.04	22/04/2008	0.02	Unknown dates troponin was 0.16 and 0.06.
Erythrocyte sedimentation rate	2-12	19/04/2008	73	

Case Number : 240841

Data Entry Date : 13/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/04/2008

Age :

DOB : 01/03/1974

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient ceased Clopine treatment due to severe neutropenia and moderate leucopenia.	Ceased Clopine.
Leukopenia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	125 Milligram Daily Oral
Batch :	Started : 01/06/2004 Stopped : 17/04/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		28/04/2008	2.50	(X10 ⁹ /L)
White blood cells		26/04/2008	3.50	(X10 ⁹ /L)
White blood cells		24/04/2008	3.10	(X10 ⁹ /L)
White blood cells		23/04/2008	2.60	(X10 ⁹ /L)
White blood cells		22/04/2008	2.70	(X10 ⁹ /L)
White blood cells		21/04/2008	3.00	(X10 ⁹ /L)
White blood cells		19/04/2008	3.00	(X10 ⁹ /L)
White blood cells		18/04/2008	3.00	(X10 ⁹ /L)
White blood cells		17/04/2008	2.80	(X10 ⁹ /L)
White blood cells		08/04/2008	4.70	(X10 ⁹ /L)
Neutrophils		28/04/2008	0.80	(X10 ⁹ /L)
Neutrophils		26/04/2008	1.30	(X10 ⁹ /L)
Neutrophils		24/04/2008	0.70	(X10 ⁹ /L)
Neutrophils		23/04/2008	0.70	(X10 ⁹ /L)
Neutrophils		22/04/2008	0.80	(X10 ⁹ /L)
Neutrophils		21/04/2008	1.00	(X10 ⁹ /L)
Neutrophils		19/04/2008	0.60	(X10 ⁹ /L)
Neutrophils		18/04/2008	0.80	(X10 ⁹ /L)
Neutrophils		17/04/2008	0.50	(X10 ⁹ /L)
Neutrophils		08/04/2008	2.10	(X10 ⁹ /L)

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		28/04/2008	0.0	(MG/DAY)
Serum drug level		26/04/2008	0.0	(MG/DAY)
Serum drug level		24/04/2008	0.0	(MG/DAY)
Serum drug level		23/04/2008	0.0	(MG/DAY)
Serum drug level		22/04/2008	0.0	(MG/DAY)
Serum drug level		21/04/2008	0.0	(MG/DAY)
Serum drug level		19/04/2008	0.0	(MG/DAY)
Serum drug level		18/04/2008	0.0	(MG/DAY)
Serum drug level		17/04/2008	125.0	(MG/DAY)
Serum drug level		08/04/2008	125.0	(MG/DAY)

Case Number : 240844

Data Entry Date : 13/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 16/04/2008

Age :

DOB : 08/09/1987

Outcome : 23/04/2008

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient ceased Clopine due to experiencing severe neutropenia.	Ceased Clopine.

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily
Batch :	Started : 12/12/2006
	Stopped : 16/04/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		24/04/2008	7.98	
White blood cells		23/04/2008	6.91	
White blood cells		22/04/2008	5.66	
White blood cells		21/04/2008	4.47	
White blood cells		20/04/2008	4.49	
White blood cells		19/04/2008	4.46	
White blood cells		18/04/2008	4.09	
White blood cells		17/04/2008	4.95	
White blood cells		16/04/2008	4.30	
White blood cells		26/03/2008	6.50	
Neutrophils		24/04/2008	3.80	
Neutrophils		23/04/2008	2.30	
Neutrophils		22/04/2008	1.80	
Neutrophils		21/04/2008	1.10	
Neutrophils		20/04/2008	0.90	
Neutrophils		19/04/2008	0.90	
Neutrophils		18/04/2008	0.90	
Neutrophils		17/04/2008	1.60	
Neutrophils		16/04/2008	1.10	
Neutrophils		26/03/2008	3.10	
Serum drug level		24/04/2008	0.0	
Serum drug level		23/04/2008	0.0	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		22/04/2008	0.0	
Serum drug level		21/04/2008	0.0	
Serum drug level		20/04/2008	0.0	
Serum drug level		19/04/2008	0.0	
Serum drug level		18/04/2008	0.0	
Serum drug level		17/04/2008	0.0	
Serum drug level		16/04/2008	0.0	
Serum drug level		26/03/2008	200.0	

Case Number : 240855

Data Entry Date : 14/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 06/03/1973

Recovered

Causality : Causality possible

Information: Current condition smoker, hypothyroidism, drug dependence cannabis abuse.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia hallucinatory and delusional symptomatology, anxiety, mood swings increase in challenging behaviours.	Ceased Clozaril
Abnormal behaviour			
Anxiety			
Delusion			
Hallucination			
Mood swings			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	Oral
Batch :	Started :
	Stopped : 15/11/2006
QUETIAPINE (Suspected)	Reason :
Batch :	Started :
	Stopped :
SODIUM VALPROATE (Suspected)	Reason : Anxiety neurosis
	4.5 Milligram Daily Oral
Batch :	Started : 04/04/2008
	Stopped :
FISH OIL NOS (Other drug)	Reason :
Batch :	Started :
	Stopped :
LITHIUM CARBONATE (Other drug)	Reason :
Batch :	Started :
	Stopped :
LORAZEPAM (Other drug)	Reason :
Batch :	Started : 15/04/2008
	Stopped :
MULTIVITAMINS (Other drug)	Reason :
Batch :	Started : 15/04/2008
	Stopped :

Medicine details :

OLANZAPINE (Other drug)

Reason :

Batch :

Started : 08/04/2008

Stopped :

TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		09/11/2006	1.0	
Neutrophils		10/11/2006	1.0	

Case Number : 240869

Data Entry Date : 14/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 27/03/2008

Age :

DOB : 27/01/1962

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Clopine ceased

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	300 Milligram Daily Oral
Batch :	Started : 17/02/2004 Stopped : 27/03/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		14/04/2008	3.10	
White blood cells		11/04/2008	3.20	
White blood cells		10/04/2008	4.80	
White blood cells		07/04/2008	6.00	
White blood cells		03/04/2008	7.70	
White blood cells		02/04/2008	8.40	
White blood cells		01/04/2008	9.30	
White blood cells		27/03/2008	7.50 mg	Dose 300
White blood cells		10/03/2008	4.80 mg	Dose 300
Neutrophils		14/04/2008	0.90	
Neutrophils		11/04/2008	0.70	
Neutrophils		10/04/2008	0.60	
Neutrophils		07/04/2008	1.30	
Neutrophils		03/04/2008	1.80	
Neutrophils		02/04/2008	1.20	
Neutrophils		01/04/2008	1.00	
Neutrophils		27/03/2008	1.10	Dose 300 mg
Neutrophils		10/03/2008	2.60	Dose 300 mg

Public Case Detail

Cases Count: 393

Case Number : 240870

Data Entry Date : 14/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 29/10/1959

Outcome :

Causality : Causality possible

Unknown

Information: Diagnosed with hepatitis C in 1997. IV drug abuse.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Twelve days after starting therapy with Clozaril the patient developed neutropenia.	
White blood cell count decreased			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	1 Dose Unspec Daily Oral
Batch :	Started : 09/02/2006 Stopped :
CLONAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
HALOPERIDOL (Other drug)	Reason :
Batch :	Started : Stopped :
METAMUCIL (Other drug)	Reason :
Batch :	Started : Stopped :
MULTI-B FORTE (Other drug)	Reason :
Batch :	Started : Stopped :
RISPERIDONE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		29/03/1996	3.60 X 10 ⁹ /L	
Neutrophils		29/03/1996	1.40 X 10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 240879

Data Entry Date : 14/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 17/06/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures while on Clopine treatment.	

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 26/12/2007	Stopped :	

Case Number : 240880

Data Entry Date : 14/05/2008

Gender : M

Hospitalisation : Hospitalisation prolonged

Weight (kg) : 0

Onset Date : 14/04/2008

Age :

DOB : 30/01/1986

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation	Elevated CK, raised liver enzymes, increased ALT and AST and increased lactate dehydrogenase.	Ceased Clopine
Alanine aminotransferase increased	Caused or prolonged inpatient hospitalisation		
Aspartate aminotransferase increased	Caused or prolonged inpatient hospitalisation		
Blood lactate dehydrogenase increased	Caused or prolonged inpatient hospitalisation		
Hepatic enzyme increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
Batch :	Started : 07/04/2008	Stopped : 14/04/2008	
AMISULPRIDE (Other drug)		Reason :	
	800 Milligram	Daily	Oral
Batch :	Started : 15/03/2008	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase				On 14/04/08 the patient's CK levels increased from 250 to 22,000.
ALT = SGPT		14/04/2008	100	
AST = SGOT		14/04/2008	376	
LDH				957

Public Case Detail

Cases Count: 393

Case Number : 240896

Data Entry Date : 14/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/12/2007

Age :

DOB : 13/02/1980

Outcome :

Causality : Causality possible

Unknown

Information: Estimated date of delivery was 14/3/08.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy		Patient became pregnant whilst on Clopine. As of 11/9/07 all was well with the pregnancy and the patient had decided to continue with the pregnancy. However, at 22 weeks of the pregnancy the patient had a spontaneous foetal abortion (miscarriage).	
Abortion spontaneous			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily Oral
Batch :	Started : 12/03/1998 Stopped : 20/07/2007

Public Case Detail

Cases Count: 393

Case Number : 241014

Data Entry Date : 20/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/04/2008

Age :

DOB : 15/02/1953

Outcome : 26/04/2008

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died from septicaemia due to ruptured appendix whilst being treated with Clopine.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	750	Daily	Oral
Batch :	Started : 30/09/1997	Stopped :	26/04/2008

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells				Patient's white cell and neutrophil counts were within normal limits for the treatment period with the exception of a few mildly rides results.
Neutrophils				Patient's white cell and neutrophil counts were within normal limits for the treatment period with the exception of a few mildly rides results.

Public Case Detail

Cases Count: 393

Case Number : 241078

Data Entry Date : 20/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/03/1944

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	Clopine ceased.

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 20/03/2008	Stopped : 03/04/2008	

Case Number : 241085

Data Entry Date : 20/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/12/2007

Age :

DOB : 02/12/1952

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Orthostatic hypotension, body mass index increased and lack of drug effect.	
Body mass index increased			
Drug ineffective			

Medicine details :

CLOZARIL (Suspected) Reason : Unspecified schizophrenia
 Tablet 400 Milligram Daily Oral
 Batch : Started : 15/12/2007 Stopped :

SODIUM VALPROATE (Suspected) Reason :
 Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				ECG revealed left anterior fascicular block, difficult to auscultate blood pressure, radial pulse poor volume,. troponin 1 increased, alkaline phosphatase increased and bilirubin increased.
Troponin	(<0.081 ug/L)	05/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	06/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	12/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	19/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	27/12/2007	1:0.08 ug/L	
Troponin	(<0.081 ug/L)	13/02/2008	1:0.08 ug/L	
Other data	(30-120 IU/L)	29/10/2007	136 IU/L	Alkaline phosphatase.
Other data	(30-120 IU/L)	13/02/2008	190 IU/L	Alkaline phosphatase.
Bilirubin		29/10/2007	136 umol/L	
Bilirubin		13/02/2008	22 umol/L	
Other data	(7-56 U/L)	18/10/2007	71	Alanine transaminase
Creatine phosphokinase	(0-5 mg/L)	15/10/2007	38.1	CRP

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	(0-5 mg/L)	18/10/2007	17.5	CRP
Creatine phosphokinase	(0-5 mg/L)	29/10/2007	34	CRP
Albumin	(34-45 g/L)	15/10/2007	30	
Albumin	(34-45 g/L)	18/10/2007	30	
Albumin	(34-45 g/L)	29/10/2007	34	
Electrocardiography		14/08/2007	Left anterior fascicular block	
Electrocardiography		15/04/2007	Left anterior fascicular block	
Echocardiogram		14/12/2007	Borderline to mild increase in relative wall thickness and reduced tissue Doppler mitral annular velocities.	

Public Case Detail

Cases Count: 393

Case Number : 241101

Data Entry Date : 22/05/2008
Hospitalisation : Admitted to hospital
Onset Date : 02/05/2008
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 66
Age :
DOB : 30/08/1976
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Myocarditis, myalgia, chest pain and feeling feverish.	Clopine ceased.
Chest pain	Life threatening		
Myalgia	Life threatening		
Pyrexia	Life threatening		
Tachycardia	Life threatening		

Medicine details :			
CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
	75 Milligram	Daily	Oral
Batch :	Started : 21/04/2008	Stopped : 02/05/2008	
OLANZAPINE (Other drug)	Reason :		
	15 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin		02/05/2008	0.12 (High)	
Erythrocyte sedimentation rate		02/05/2008	ESR raised	
White blood cells		02/05/2008	White count raised	
Other data		02/05/2008	Tachycardia 125	

Public Case Detail

Cases Count: 393

Case Number : 241142

Data Entry Date : 23/05/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 30/04/2008

Age : 49Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Troponin increased	Caused or prolonged inpatient hospitalisation	Troponin rise.	Ceased Clozapine.

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
125 Milligram Daily	
Batch :	Started : 09/04/2008 Stopped : 09/04/2008
DIAZEPAM (Other drug)	Reason :
10 Milligram Daily	
Batch :	Started : L TERM Stopped :
OLANZAPINE (Other drug)	Reason :
30 Milligram Daily	
Batch :	Started : L TERM Stopped : 0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		30/04/2008	0.26 mcg/L	
Troponin		29/04/2008	0.48 mcg/L	

Public Case Detail

Cases Count: 393

Case Number : 241383

Data Entry Date : 30/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 26Y

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pneumonia		pneumonia	

Medicine details :			
CLOPINE (Suspected)	Reason :		
	500 Milligram	Daily	Oral
Batch :	Started : 20/01/2006	Stopped : 01/05/2008	

Public Case Detail

Cases Count: 393

Case Number : 241467

Data Entry Date : 02/06/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 09/04/2008

Age :

DOB : 11/04/1935

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	Dantrolene

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
		75 Milligram	Daily
Batch :	Started :	S TERM	Stopped : 09/04/2008

Public Case Detail

Cases Count: 393

Case Number : 241508

Data Entry Date : 03/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/04/2008

Age :

DOB : 19/05/1980

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased Clopine treatment due to experiencing myocarditis.	Ceased Clopine

Medicine details :

CLOPINE (Suspected)	Reason :		
	25 Milligram	Daily	Oral
Batch :	Started : 11/04/2008	Stopped :	01/05/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				The patient's white blood cell and neutrophil counts were generally elevated throughout treatment.

Case Number : 241509

Data Entry Date : 03/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/04/2008

Age :

DOB : 02/11/1977

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased Clopine treatment due to experiencing Myocarditis.	Ceased Clopine.

Medicine details :

CLOPINE (Suspected) Reason :
200 Milligram Daily Oral
Batch : Started : 25/03/2008 Stopped : 08/04/2008

AMISULPRIDE (Other drug) Reason :
600 Milligram
Batch : Started : Stopped :

HALDOL DECANOATE (Other drug) Reason :
100 Milligram
Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		06/02/2008	376 U/L	
GGT = SGGT = GGTP		06/02/2008	102 U/L	
Ultrasound		26/02/2008	Normal	Upper abdominal ultrasound
Electrocardiography		07/04/2008	Sinus tachycardia	
Troponin		07/04/2008	0.40	
Troponin		08/04/2008	0.54	
Creatine kinase MB				Normal
Echocardiogram		08/04/2008	Abnormal (suggestion of some apico-septal, infero-septal and lateral hypokinesis)	

Case Number : 241526

Data Entry Date : 03/06/2008
Hospitalisation : Admitted to hospital
Onset Date : 06/05/2008
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 68
Age :
DOB : 21/07/1979
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increased	Caused or prolonged inpatient hospitalisation	Increased ALT and AST	Ceased Clopine
Aspartate aminotransferase increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia
125 Milligram Daily Oral	
Batch :	Started : Stopped :
OLANZAPINE (Suspected)	Reason : Unspecified schizophrenia
30 Milligram Daily Oral	
Batch :	Started : Stopped :
AMISULPRIDE (Other drug)	Reason :
Batch :	Started : Stopped :
DIAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
LORAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
THIAMINE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		11/04/2008	303	?? May - ALT 509
ALT = SGPT		28/04/2008	58	?? May - ALT 509
ALT = SGPT		06/05/2008	470	?? May - ALT 509
AST = SGOT		11/04/2008	99	
AST = SGOT		06/05/2008	199	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
GGT = SGGT = GGTP		28/04/2008	52	

Case Number : 241529

Data Entry Date : 03/06/2008
Hospitalisation : Admitted to hospital
Onset Date : 06/05/2008
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 68
Age :
DOB : 21/07/1979
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increased	Caused or prolonged inpatient hospitalisation	Increased ALT and AST	Ceased Clozapine
Aspartate aminotransferase increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
100 Milligram Daily Oral	
Batch :	Started : 29/04/2008 Stopped :
OLANZAPINE (Suspected)	Reason : Unspecified schizophrenia
30 Milligram Daily Oral	
Batch :	Started : Stopped :
AMISULPRIDE (Other drug)	Reason :
Batch :	Started : Stopped :
DIAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
LORAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
THIAMINE (Other drug)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		11/04/2008	303	?? May 08 - ALT 509
ALT = SGPT		28/04/2008	58	?? May 08 - ALT 509
ALT = SGPT		06/05/2008	470	?? May 08 - ALT 509
AST = SGOT		11/04/2008	99	
AST = SGOT		06/05/2008	199	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
GGT = SGGT = GGTP		28/04/2008	52	

Public Case Detail

Cases Count: 393

Case Number : 241542

Data Entry Date : 04/06/2008
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 16/08/1969
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cellulitis	Caused or prolonged inpatient hospitalisation	Cellulitis and the infection becoming possibly septic.	Clopine ceased. Amitted to ICU.
Sepsis	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	650 Milligram	Daily	Oral
Batch :	Started : 12/11/2007	Stopped : 02/04/2008	

Public Case Detail

Cases Count: 393

Case Number : 241545

Data Entry Date : 04/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/05/2008

Age :

DOB : 28/07/1939

Outcome : 01/05/2008

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 30/01/2008	Stopped :	

Case Number : 241562

Data Entry Date : 04/06/2008

Gender : F

Hospitalisation : Required a specialist consultation

Weight (kg) : 0

Onset Date : 20/04/2004

Age :

DOB : 13/07/1954

Outcome :

Causality : Causality possible

Unknown

Information: History of monocytosis and cough.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Caused or prolonged inpatient hospitalisation	Leukopenia, neutropenia, thrombocytopenia, haematocrit decreased, monocytosis, cough and leukocytosis.	
Cough	Caused or prolonged inpatient hospitalisation		
Haematocrit decreased	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Monocytosis	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	300 Milligram Daily Oral
Batch :	Started : 18/09/2000 Stopped : 09/05/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		18/09/2000	6.6x10 ⁹ /L	
Neutrophils		20/10/2004	0.70x10 ⁹ /L	
Neutrophils		27/12/2005	1.4x10 ⁹ /L	
Neutrophils		28/12/2008	1.52x10 ⁹ /L	
Neutrophils		30/12/2008	1.49x10 ⁹ /L	
Neutrophils		03/06/2006	3.61x10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 241568

Data Entry Date : 04/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/05/2008

Age :

DOB : 20/08/1974

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and leucopenia.	Ceased Clopine
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 22/05/2006	Stopped :	12/05/2008

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		16/05/2008	3.30	
White blood cells		15/05/2008	2.80	
White blood cells		14/05/2008	3.20	
White blood cells		12/05/2008	5.00	
White blood cells		09/05/2008	4.60	
Neutrophils		16/05/2008	0.70	
Neutrophils		15/05/2008	0.70	
Neutrophils		14/05/2008	1.10	
Neutrophils		12/05/2008	1.20	
Neutrophils		09/05/2008	2.20	

Case Number : 241585

Data Entry Date : 04/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/04/2008

Age :

DOB : 16/08/1958

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Splenomegaly	Caused or prolonged inpatient hospitalisation	Patient experienced mild splenomegaly, Troponin raised, borderline billirubin and low platelet count.	Clozaril discontinued.
Blood bilirubin abnormal	Caused or prolonged inpatient hospitalisation		
Eosinophil count increased	Caused or prolonged inpatient hospitalisation		
Heart rate increased	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		
Platelet count decreased	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet 100 Milligram Daily Oral

Batch : Started : 07/04/2008 Stopped : 29/04/2008 0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		29/04/2008	0.27	
Troponin		01/05/2008	0.06	
Troponin		06/05/2008	0.48	
Bilirubin		29/04/2008	20	
Bilirubin		01/05/2008	-	
Bilirubin		06/05/2008	-	
Heart Rate		29/04/2008	-	
Heart Rate		01/05/2008	-	
Heart Rate		06/05/2008	136	

Public Case Detail

Cases Count: 393

Case Number : 241614

Data Entry Date : 05/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/05/2008

Age :

Outcome : 09/05/2008

DOB : 17/01/1958

Death

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Male patient died due to unknown reasons whilst being treated with Clopine.	

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 13/04/2006	L TERM	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 241625

Data Entry Date : 05/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome : 04/03/2008

DOB : 29/03/1981

Recovered

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug level increased		High clozapine levels.	Reducing clozapine.

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	375 Milligram	Daily	Oral
Batch :	Started : 04/11/2002	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		11/02/2008	1300	Clozapine level
Serum drug level		11/02/2008	560	Clozapine level
Serum drug level		11/02/2008	430	Clozapine level
Serum drug level		11/02/2008	380	Clozapine level

Public Case Detail

Cases Count: 393

Case Number : 241662

Data Entry Date : 06/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/05/2008

Age :

DOB : 09/07/1934

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		switched from Clozapine to Clopine and experienced neuroleptic malignant syndrome	ceased drug

Medicine details :			
CLOPINE (Suspected)	Reason :		
	150 Milligram	Daily	Oral
Batch :	Started : 07/02/2008	Stopped : 04/05/2008	

Public Case Detail

Cases Count: 393

Case Number : 241821

Data Entry Date : 12/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 01/04/1966

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 23/04/2008	Stopped :	09/05/2008

Public Case Detail

Cases Count: 393

Case Number : 241822

Data Entry Date : 12/06/2008

Hospitalisation :

Onset Date : 31/12/2007

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 01/03/1976

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy and ejection fraction decreased.	Clopine ceased.

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 15/03/2004	L TERM	Stopped : 01/04/2008

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				Reduction in ejection fraction to 42%. Follow up cardiology review showed ejection fraction had improved to 59%.

Public Case Detail

Cases Count: 393

Case Number : 241836

Data Entry Date : 12/06/2008
Hospitalisation : Admitted to hospital
Onset Date : 12/05/2008
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 17/05/1977
Causality : Causality possible

Information: Further information - Medical history included viral infection (? EBV), drug abuse (recreational use of tetrahydrocannabinol, cocaine, amphetamine), high HDL, obesity. The pt smoked 15 cigarettes per day.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Patient experienced a cardiac arrest and myocarditis.	Clozaril was discontinued.
Chest pain	Life threatening	Pt experienced chest pain - severe anterior, central sharp, stabbing in character and worse on deep inspiration - No change with posture, radiation; dyspnoea for 5 days. The chest pain was accompanied by vomiting. Pt's eosinophilic count , troponin T value and C-reactive proteins was increased. Pt was also prescribed zuclopenthixol depot (Clopixol) but was ceased because of extrapyramidal side effects. Pt later developed tachycardia	Clozaril was discontinued and risperidone initiated. Also was treated with atorvastatin and NSAID.
Akathisia	Life threatening		
C-reactive protein increased	Life threatening		
Cardiac arrest	Life threatening		
Eosinophil count increased	Life threatening		
Extrapyramidal disorder	Life threatening		
Musculoskeletal stiffness	Life threatening		
Myocarditis	Life threatening		
Pyrexia	Life threatening		
Sinus tachycardia	Life threatening		
Troponin T increased	Life threatening		
Vomiting	Life threatening		

Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

300 Milligram Daily

Batch :

Started : 13/04/2008

Stopped : 12/05/2008

0

ZUCLOPENTHIXOL DECANOATE (Suspected)

Reason :

Batch :

Started :

Stopped :

ATORVASTATIN (Other drug)

Reason :

Batch :

Started :

Stopped :

RISPERIDONE (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Normal with trivial physiological regurgitation and 42% left ventricular ejection fraction.
Chest X-ray				Essential segmental atelectasis right lower lobe.
C-Reactive Protein	<10	12/05/2008	152	High
C-Reactive Protein	<10	17/05/2008	74	High
Eosinophils	0.2 - 0.8 x 10 ⁹ /L	17/05/2008	1.34	High
Troponin	<0.02	12/05/2008	0.488	Troponin T - High
Troponin	<0.02	13/05/2008	0.529	Troponin T - High
Troponin	<0.02	14/05/2008	0.082	Troponin T - High
Troponin	<0.02	15/05/2008	0.05	Troponin T - High
Other data				EBV antibody was positive on 17 May 2008.

Public Case Detail

Cases Count: 393

Case Number : 241838

Data Entry Date : 12/06/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 08/05/2008

Age :

DOB : 22/06/1944

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced seizure.	Epilium and valproate.

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
	800 Milligram Daily
Batch :	Started : 13/07/2005 Stopped :

Public Case Detail

Cases Count: 393

Case Number : 241990

Data Entry Date : 17/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 16/05/2008

Age :

Outcome : 16/05/2008

DOB : 16/10/1965

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Grand mal seizures.	Clozapine and fluoxetine withheld. Treated with intravenous diazepam 5mg.

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	600 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
FLUOXETINE HYDROCHLORIDE (Suspected)		Reason : Depression	
Capsule	20 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 242043

Data Entry Date : 18/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 31/03/1981

Outcome :

Causality : Causality possible

Unknown

Information: Current condition Diabetes (Diabetes mellitus); diagnosed prior to commencement of Clozaril.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased		Patient experienced elevated blood sugar levels.	

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started :	S TERM	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 242056

Data Entry Date : 18/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/05/2008

Age :

DOB : 09/08/1976

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Possible cardiomyopathy.	Ceased Clopine. Commenced Coversyl (perindopril) and metoprolol.

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
	450 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Case Number : 242058

Data Entry Date : 19/06/2008
Hospitalisation : Admitted to hospital
Onset Date : 04/05/2008
Outcome :
 Recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 09/07/1934
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome: febrile, tachycardic, sweating, dystonic, rigidity	stopped: efexor, clopine, benztropine; treated with bromocriptine.

Medicine details :

BENZTROPINE MESYLATE (Suspected)	Reason :
Batch :	Started :
	Stopped : 04/05/2008 0
CLOPINE (Suspected)	Reason :
Batch :	Started :
	Stopped :
EFEXOR (Suspected)	Reason : Depression
Batch :	Started :
	Stopped : 04/05/2008
TRIMETHOPRIM (Other drug)	Reason :
Batch :	Started : 24/04/2008
	Stopped : 05/05/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		04/08/2008	2810	

Public Case Detail

Cases Count: 393

Case Number : 242110

Data Entry Date : 19/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 16/05/2008

Age :

DOB : 18/07/1954

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and leucopenia	
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
Batch :	Started : 14/01/2008	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		29/05/2008	2.60	
White blood cells		28/05/2008	2.70	
White blood cells		27/05/2008	2.60	
White blood cells		23/05/2008	2.70	
White blood cells		20/05/2008	2.50	
White blood cells		16/05/2008	2.60	
White blood cells		08/05/2008	3.50	
White blood cells		01/05/2008	4.90	
Neutrophils		29/05/2008	0.90	
Neutrophils		28/05/2008	0.90	
Neutrophils		27/05/2008	0.70	
Neutrophils		23/05/2008	0.60	
Neutrophils		20/05/2008	0.80	
Neutrophils		16/05/2008	1.50	
Neutrophils		08/05/2008	2.10	
Neutrophils		01/05/2008	3.00	

Public Case Detail

Cases Count: 393

Case Number : 242213

Data Entry Date : 24/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/04/2008

Age :

DOB : 17/07/1974

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Suspected myocarditis.	Clopine ceased.

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 17/04/2008	Stopped : 30/04/2008	

Public Case Detail

Cases Count: 393

Case Number : 242221

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2008

Age :

DOB : 20/06/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	clopine ceased.

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 14/05/2008	Stopped :	21/05/2008

Public Case Detail

Cases Count: 393

Case Number : 242226

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/05/2008

Age :

DOB : 30/09/1959

Outcome : 22/05/2008

Causality : Causality possible

Unrelated death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 31/05/2004	Stopped : 22/05/2008	

Public Case Detail

Cases Count: 393

Case Number : 242243

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 15/08/1939

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased		White cell and neutrophil counts were elevated.	Ceased Clopine
Neutrophil count increased			
Pneumonia			

Medicine details :

CLOPINE (Suspected)	Reason :
	200 Milligram Daily Oral
Batch :	Started : 06/02/2008 Stopped : 02/06/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		03/06/2008	15.25	x 10 ⁹ /L
White blood cells		06/05/2008	13.00	x 10 ⁹ /L
Neutrophils		03/06/2008	12.60	10 ⁹ /L
Neutrophils		06/05/2008	9.40	10 ⁹ /L

Public Case Detail

Cases Count: 393

Case Number : 242245

Data Entry Date : 25/06/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 01/06/2008

Age :

DOB : 21/08/1981

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed a temperature (38C), tachycardia and hypotension. A transthoracic echocardiogram (TTE) showed decreased left ventricular function. The patient was diagnosed with clozapine induced myocarditis.	Clopine ceased.

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
Batch :	Started : 19/05/2008 Stopped : 01/06/2008
LITHIUM CARBONATE (Other drug)	Reason :
	1.8 Milligram Daily
Batch :	Started : Stopped :

Case Number : 242247

Data Entry Date : 25/06/2008
Hospitalisation : Admitted to hospital
Onset Date : 22/05/2008
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 19/08/1982
Causality : Causality certain

Information: Cert:rechall
 Commenced Clopine again on 13 Dec 2008 and experienced myocarditis again.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Suspected early myocarditis.	Ceased clopine.

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 03/05/2008	Stopped : 22/05/2008	
AMISULPRIDE (Other drug)	Reason :		
	700 Milligram	Daily	
Batch :	Started :	Stopped :	
QUETIAPINE (Other drug)	Reason :		
	300 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				Relevant tests: 22/05/08 - Troponin 0.07;
				??/05/08 - Troponin <0.05 (Normal)
				22/05/08 - Cardiac Exam NAD
				??/05/08 - Echocariogram Normal

Public Case Detail

Cases Count: 393

Case Number : 242252

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 03/06/2008

Age :

DOB : 25/02/1979

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Eosinophilia	Caused or prolonged inpatient hospitalisation	Eosinophilia and increased white blood cell levels and neutrophil counts.	
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia		
Tablet	150 Milligram	Daily	Oral
Batch :	Started : 22/04/2008	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils	7.7-1.8 x10 ⁹ /L			Neutrophil count increased High 9.3 x 10(9)/L
White blood cells	11.0 - 4.5 x 10 ⁹ /L			19.3 x 10 ⁹ /L
Eosinophils				High - 1.4 x 10 ⁹ /L

Case Number : 242254

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/05/1955

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Platelet count increased		Platelet count increased.	Clozaril discontinued

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	275 Milligram Daily Oral
Batch :	Started : 25/10/2007 Stopped : 28/11/2007
BENZTROPINE MESYLATE (Other drug)	Reason :
Batch :	Started : 15/05/2007 Stopped :
CLONAZEPAM (Other drug)	Reason :
Batch :	Started : Stopped :
MORPHINE NOS (Other drug)	Reason :
Batch :	Started : Stopped :
THIORIDAZINE HYDROCHLORIDE (Other drug)	Reason :
Batch :	Started : 15/03/2007 Stopped : 10/11/2007
VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason :
Batch :	Started : 15/04/2006 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Platelets		19/11/2007	466 x 10 ⁹ /L	
Platelets		28/11/2007	611 x 10 ⁹ /L	
Platelets		29/11/2007	599 x 10 ⁹ /L	
Platelets		13/12/2007	329 x 10 ⁹ /L	
Platelets		21/12/2007	258 x 10 ⁹ /L	
Platelets		14/01/2008	267 x 10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 242259

Data Entry Date : 25/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 05/04/1974

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hepatic necrosis		Tired, red, raised, scaly rash - almost psoriatic, hepatic necrosis.	
Fatigue			
Rash			
Rash erythematous			

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Case Number : 242261

Data Entry Date : 25/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 27/06/1935

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hypotension		Hypotension	Clozaril discontinued.

Medicine details :			
ASPIRIN (Suspected)		Reason :	
	150 Milligram	Daily	
Batch :	Started :	Stopped :	
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 14/04/2008	Stopped : 02/05/2008	
AMLODIPINE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
CARBAMAZEPINE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
DIAZEPAM (Other drug)		Reason :	
Batch :	Started :	Stopped :	
METFORMIN HYDROCHLORIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
PERINDOPRIL (Other drug)		Reason :	
Batch :	Started :	Stopped :	
THYROXINE SODIUM (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 242295

Data Entry Date : 25/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 24/04/2006

Age :

DOB : 12/06/1981

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		"Really raised GGT, ALT and AST", fever.	
Protein total increased			
Pyrexia			

Medicine details :

CLOZARIL (Suspected) Reason : Unspecified schizophrenia
 Tablet 300 Milligram Daily Oral

Batch : Started : 03/04/2006 Stopped :

OLANZAPINE (Other drug) Reason :

Batch : Started : Stopped :

SODIUM VALPROATE (Other drug) Reason :

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT				High - 101
AST = SGOT				High - 54
GGT = SGGT = GGTP				371
Protein				High - 92

Case Number : 242311

Data Entry Date : 26/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 07/04/2008

Age :

DOB : 16/01/1970

Outcome :

Causality : Causality possible

Death

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient complained of having recent onset of seizures. His GP thought these were due to postural hypotension. Patient had been on treatment with clozapine from 02 Aug 2000 and switched to Clopine Brand on 25 March 2008. He died during his sleep on 07 April 2008. Death is unexplained; father of patient attributes it to seizures.	
Convulsion	Death		

Medicine details :

CLOPINE (Suspected)		Reason :	
	400	Daily	Oral
Batch :	Started : 25/03/2000	Stopped : 06/04/2008	
CLOZAPINE (Suspected)		Reason :	
	400 Milligram	Daily	Oral
Batch :	Started : 02/08/2000	Stopped : 24/03/2008	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				

Public Case Detail

Cases Count: 393

Case Number : 242333

Data Entry Date : 26/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 02/10/1974

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 09/05/2008	Stopped : 26/05/2008	

Public Case Detail

Cases Count: 393

Case Number : 242337

Data Entry Date : 27/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 23/01/1973

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Seizures while on Clopine.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 19/03/2008	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 242352

Data Entry Date : 27/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 04/05/2008

Age :

Outcome :

DOB : 08/10/1991

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain and hypotension.	
Bundle branch block bilateral	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation		
Hypotension			

Medicine details :			
CLOZARIL (Suspected)		Reason : Schizophrenia	
Tablet	125 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0

Public Case Detail

Cases Count: 393

Case Number : 242377

Data Entry Date : 30/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/05/2008

Age :

DOB : 27/03/1974

Outcome : 20/05/2008

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	Clopine ceased.

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	50 Milligram	Daily	Oral
Batch :	Started : 17/05/2008	Stopped : 19/05/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin		19/05/2008	0.08 U/L	Troponin
C-Reactive Protein		19/05/2008	83 M/G/L	CRP
Creatine phosphokinase		19/05/2008	Normal	CK
Temperature		19/05/2008	38.5c	Fever

Case Number : 242386

Data Entry Date : 30/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 25/05/2008

Age :

Outcome :

DOB : 18/06/1966

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		seizure	
Unresponsive to stimuli			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia	
500 Milligram	Daily	Oral
Batch :	Started : 03/01/1996	Stopped :
BENZTROPINE MESYLATE (Other drug)	Reason :	
Batch :	Started :	Stopped :
LACTULOSE (Other drug)	Reason :	
Batch :	Started :	Stopped :
MULTIVITAMINS (Other drug)	Reason :	
Batch :	Started :	Stopped :
PROPRANOLOL HYDROCHLORIDE (Other drug)	Reason :	
Batch :	Started :	Stopped :
SODIUM VALPROATE (Other drug)	Reason :	
Batch :	Started :	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 242509

Data Entry Date : 01/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/06/2008

Age :

DOB : 18/12/1976

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient suffered from cardiac complications - pericarditis/myocarditis.	
Myocarditis			
Neutrophil count decreased			
White blood cell count decreased			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 24/05/2008	Stopped :	09/06/2008

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Neutrophils		17/05/2008	5.5*10 ⁹	
Neutrophils		07/06/2008	3.5*10 ⁹	
White blood cells		17/05/2008	7.7*10 ⁹	
White blood cells		07/06/2008	4.60*10 ⁹	

Public Case Detail

Cases Count: 393

Case Number : 242691

Data Entry Date : 08/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 10/10/1972

Outcome :

Causality : Causality possible

Unknown

Information: The patient's white blood cell counts and neutrophil counts were within normal ranges throughout treatment.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis.	Ceased Clopine.

Medicine details :

CLOPINE (Suspected)	Reason :	
Tablet	1 Dose Unspec Daily	Oral
Batch :	Started : 23/04/2008	Stopped : 10/05/2008

Case Number : 242695

Data Entry Date : 08/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 20/06/2008

Age :

DOB : 06/10/1982

Outcome :

Causality : Causality probable

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Clopine ceased.
Leukopenia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily Oral
Batch :	Started : 10/05/2007 Stopped : 20/06/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		22/06/2008	3.00	(X10 ⁹ /L)
White blood cells		20/06/2008	2.10	(X10 ⁹ /L)
White blood cells		30/05/2008	4.10	(X10 ⁹ /L)
Neutrophils		22/06/2008	2.01	(X10 ⁹ /L)
Neutrophils		20/06/2008	0.80	(X10 ⁹ /L)
Neutrophils		30/05/2008	2.60	(X10 ⁹ /L)
Serum drug level		22/06/2008	0.0	(MG)
Serum drug level		20/06/2008	0.0	(MG)
Serum drug level		30/05/2008	200.0	(MG)

Public Case Detail

Cases Count: 393

Case Number : 242820

Data Entry Date : 11/07/2008
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 08/01/1974
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Urinary tract infection	Caused or prolonged inpatient hospitalisation	Patient developed a "urinary sepsis".	Withheld Clopine for 2 days and recommenced on the 12/06/2008 at a dose of 12.5mg/daily.

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 07/06/2006	Stopped :	0

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		17/06/2008	9.03 x10 ⁹ /L	WCC
White blood cells		12/06/2008	20.00	WCC
Neutrophils		17/06/2008	6.47 x 10 ⁹ /L	Neut - MG = 125.0 and 12.5
Neutrophils		12/06/2008	16.28	Neut - MG = 125.0 and 12.5

Public Case Detail

Cases Count: 393

Case Number : 242851

Data Entry Date : 11/07/2008

Gender : F

Hospitalisation : Required a specialist consultation

Weight (kg) : 67

Onset Date :

Age :

DOB : 11/08/1972

Outcome : 29/04/2008

Causality : Causality probable

Recovered

Information: The patient's white cell and neutrophil counts were within the normal ranges throughout treatment.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia and ST segment depression.	Treated with metoprolol. Clopine dose reduced.
Electrocardiogram ST segment depression	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)

Reason :

Tablet

450 Milligram

Daily

Oral

Batch :

Started : 03/03/2006

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Repeat echocardiogram, which was normal. Cardiac enzymes were also normal.

Public Case Detail

Cases Count: 393

Case Number : 243028

Data Entry Date : 18/07/2008

Hospitalisation :

Onset Date : 11/08/2006

Outcome :
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 12/11/1967

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		This patient was taking Clozaril for an unspecified indication and had discontinued and recommenced treatment five times since 15/06/1999.	Clozaril was discontinued and was being re-started at the time of the report.

Medicine details :

CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 16/10/2003	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Patient's annual echo showed mild global hypokinesia with Clozaril cardiomyopathy.

Public Case Detail

Cases Count: 393

Case Number : 243196

Data Entry Date : 24/07/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 01/10/1965

Outcome :

Causality : Causality possible

Unknown

Information: White blood cell and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy	Clopine ceased.

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
Batch :	Started : 17/01/2007	Stopped : 06/06/2008	

Case Number : 243208

Data Entry Date : 24/07/2008
Hospitalisation : Admitted to hospital
Onset Date : 16/03/2008
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 25/07/1971
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Myocarditis secondary to Clozapine.	All meds ceased.
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason :
Tablet	125 Milligram Daily Oral
Batch :	Started : 03/03/2008 Stopped : 16/03/2008
FLUPENTHIXOL DECANOATE (Other drug)	Reason :
Batch :	Started : Stopped :
LITHIUM CARBONATE (Other drug)	Reason :
	500 Milligram Daily Oral
Batch :	Started : Stopped : 16/03/2008
OLANZAPINE (Other drug)	Reason :
	20 Milligram Daily Oral
Batch :	Started : Stopped : 16/03/2008
SERTRALINE HYDROCHLORIDE (Other drug)	Reason :
	50 Milligram Daily Oral
Batch :	Started : 19/02/2008 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				17/03/08 - temperature was 37-39 C, tachy = 110. troponin = 01.31, K= =3.9. Na+ =134, creatinine = 68 on 16/03/08

Case Number : 243338

Data Entry Date : 30/07/2008

Gender : F

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Age : 34Y

Onset Date :

DOB :

Outcome :

Causality : Causality probable

Recovered

Information: History of bizarre behaviour and auditory hallucinations. 24d. Report Source Literature. Journal: Australian and New Zealand Journal of Psychiatry. Author: Caetano D, Gandhi C. Title: Clozapine-induced myocarditis. Volume: 42(5) Year: 2008. Pages: 434-435.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis, electrocardiogram QT prolonged, tachycardia, pyrexia, white blood cell count increased, C-reactive protein increased, troponin T increased, eosinophil count increased, nausea and dizziness.	Clozapine ceased.
C-reactive protein increased			
Dizziness			
Electrocardiogram QT prolonged			
Eosinophil count increased			
Nausea			
Neutrophil count increased			
Pyrexia			
Red blood cell sedimentation rate increased			
Tachycardia			
Troponin I increased			
Troponin T increased			
White blood cell count increased			

Medicine details :

CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 125 Milligram Daily Oral

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood culture	70			Blood creatine phosphokinase 54IU/l week 2 + 4 days of clozapine treatment.

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
C-Reactive Protein	10			C-reactive protein high week 2 + 4 days of clozapine treatment. 117.8 mg/L. C-reactive protein high at emergency department. 98 mg/L
Electrocardiography				Electrocardiogram QT interval baseline 428. Electrocardiogram QT interval week 2 of clozapine treatment 506. Electrocardiogram QT interval week 2 + 4 days of clozapine treatment 503.
Neutrophils				Neutrophil count week 2 + 4 days of clozapine treatment 9.6×10^9 .
Red blood cells	20			Red blood cell sedimentation rate week 2 + 4 days of clozapine treatment 81 mm/h
Troponin	0.05			Troponin I 0.243. Troponin T at emergency department.
Other data				Test/assessment/notes week 2 + 4 days of clozapine treatment.
White blood cells				White blood cell count week 2 + 4 days of clozapine treatment 12.1×10^9 . White blood cell count at emergency department 10.9×10^9 .

Case Number : 243376

Data Entry Date : 31/07/2008
Hospitalisation : Admitted to hospital
Onset Date : 04/06/2008
Outcome : 18/06/2008
 Recovered

Gender : M
Weight (kg) : 113
Age :
DOB : 17/10/1948
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Acute myocardial infarction	Caused or prolonged inpatient hospitalisation	Acute myocardial infarction	Coronary artery bypass graft

Medicine details :

CLOPINE (Suspected) Reason : Unspecifid affective psychosis

Tablet 300 Milligram Daily Oral

Batch : Started : Stopped :

CLOZARIL (Suspected) Reason : Unspecifid affective psychosis

Oral

Batch : Started : 30/03/1995 Stopped : 07/06/2008

ASPIRIN (Other drug) Reason :

Batch : Started : Stopped :

ATORVASTATIN (Other drug) Reason :

Batch : Started : Stopped :

BENZTROPINE MESYLATE (Other drug) Reason :

Batch : Started : Stopped :

METFORMIN HYDROCHLORIDE (Other drug) Reason :

Batch : Started : Stopped :

METOPROLOL TARTRATE (Other drug) Reason :

Batch : Started : Stopped :

PROTAPHANE (Other drug) Reason :

Batch : Started : Stopped :

RAMIPRIL (Other drug) Reason :

Batch : Started : Stopped :

Medicine details :

VENLAFAXINE HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Coronary angiogram				It was found that the patient had normal left ventricular contraction with ejection fraction of less than 60%. No stenosis in the left main coronary artery, diffuse moderate disease with focal stenosis of 90% proximal left anterior descending, left circumflex 95% proximal stenosis, right coronary artery mild diffuse irregularities with focal stenosis 80%.

Public Case Detail

Cases Count: 393

Case Number : 243389

Data Entry Date : 01/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/07/2008

Age :

DOB : 24/04/1966

Outcome :

Causality : Causality certain

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Clopine ceased 01/07/08
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 05/06/2001	Stopped : 01/06/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		04/07/2008	4.00	
White blood cells		03/07/2008	3.80	
White blood cells		02/07/2008	2.40	
White blood cells		01/07/2008	2.30	
White blood cells		04/06/2008	5.70	
Neutrophils		04/07/2008	1.50	
Neutrophils		03/07/2008	1.30	
Neutrophils		02/07/2008	1.00	
Neutrophils		01/07/2008	0.90	
Neutrophils		04/06/2008	3.00	

Public Case Detail

Cases Count: 393

Case Number : 243393

Data Entry Date : 01/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/06/2008

Age :

DOB : 01/06/1989

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		Patient took an overdose of Clopine and was found unconscious on 19/06/08.	
Intentional overdose			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	500 Milligram	Daily	Oral
Batch :	Started : 28/11/2007	Stopped :	30/04/2008

Public Case Detail

Cases Count: 393

Case Number : 243396

Data Entry Date : 01/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 14/08/1965

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient commenced treatment with Clozapine on 12/09/1994 and was switched to Clopine brand on 05/02/04. He was titrated up to PO 800mg daily, but was taking 300mg PO daily around the time of the event. On an unknown date in 2008, the patient experienced seizures and pinpoint pupils and was reported to be delirious. It was suspected that the patient had taken an overdose of Clopine. It was also noted that the patient was non-compliant.	
Delirium			
Overdose			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	300 Milligram Daily Oral
Batch :	Started : 05/02/2004 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				The patient's white cell and neutrophil counts were within normal ranges for the treatment period with the exception of a few slightly raised counts on occasion.

Public Case Detail

Cases Count: 393

Case Number : 243422

Data Entry Date : 01/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/07/2008

Age :

DOB : 29/06/1987

Outcome : 19/07/2008

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest pain		Patient complained of chest pain. T wave inversion.	
Electrocardiogram T wave inversion			

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
	200 Milligram	Daily	
Batch :	Started : 01/07/2008	Stopped : 19/07/2008	

Public Case Detail

Cases Count: 393

Case Number : 243427

Data Entry Date : 01/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 15/09/1962

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Ceased Clopine treatment due to experiencing myocarditis.	Ceased Clopine

Medicine details :

CLOPINE (Suspected)	Reason :		
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 29/05/2008	Stopped : 09/07/2008	

Public Case Detail

Cases Count: 393

Case Number : 243428

Data Entry Date : 01/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 29/06/1947

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient ceased Clopine treatment due to seizures.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	650 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped : 0

Public Case Detail

Cases Count: 393

Case Number : 243429

Data Entry Date : 01/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 25/06/2008

Age :

DOB : 26/02/1959

Outcome : 25/06/2008

Causality : Causality probable

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Ceased Clopine treatment due to experiencing myocarditis.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified psychosis	
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 02/06/2008	Stopped : 25/06/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Creatine kinase MB		25/06/2008	Elevated	
Troponin		25/06/2008	Abnormal	

Case Number : 243540

Data Entry Date : 06/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/05/2008

Age :

DOB : 01/04/1966

Outcome :

Causality : Causality probable

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Became febrile 38.2 degrees, with sinus tachycardia	Ceased Clozapine and Quetiapine dose increased to 200mg nocte.

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started :	Stopped :	10/05/2008 0
QUETIAPINE (Other drug)		Reason : Unspecified schizophrenia	
	100 Milligram	Total	Oral
Batch :	Started :	Stopped :	
ZUCLOPENTHIXOL ACETATE (Other drug)		Reason :	
Injection	300 Milligram		
Batch :	Started :	Stopped :	
	09/05/2008		

Public Case Detail

Cases Count: 393

Case Number : 243613

Data Entry Date : 07/08/2008

Gender : M

Hospitalisation : Treated in outpatient department only.

Weight (kg) : 0

Onset Date :

Age : 53Y

Outcome :

DOB :

Not yet recovered

Causality : Causality certain

Information: Cert (Rechall)

Three weeks after the commencement of Clozapine with concurrent laxative administration, the patient developed a further episode of severe constipation with faecal impaction.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Treated in outpatient department only	53 year old single Caucasian male who presented to the emergency department with severe abdominal pain and bilious vomiting. On examination in emergency department, patient was drowsy, sweaty, afebrile, tachycardic and hypotensive. His abdomen was distended and he had severe generalised abdominal pain. His vomitus was bilious and had an offensive odour. Olanzapine and lithium were gradually re-introduced after 10 days as he showed signs of a relapse of his schizoaffective disorder. Clozapine was gradually re-introduced and increased to a dose of 350 mg/day in two divided doses.	Manual bowel disimpaction was performed. All his medications were ceased. Lactulose and docusate sodium (coloxyl with senna) were prescribed concurrently in liason with a gastroenterologist. The clozapine was ceased. His normal bowel movements resumed after several fleet enemas. He was commenced on risperidone 2mg once a day. The patient continues to be thought-disordered with elevated mood. He requires a weekly fleet enema.
Abdominal distension	Treated in outpatient department only		
Hyperhidrosis	Treated in outpatient department only		
Hypotension	Treated in outpatient department only		
Intestinal dilatation	Treated in outpatient department only		
Somnolence	Treated in outpatient department only		
Tachycardia	Treated in outpatient department only		
Vomiting	Treated in outpatient department only		

Medicine details :

CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 700 Milligram Daily Oral

Batch : Started : Stopped :

IRON ORAL NOS (Other drug)

Reason :

Batch : Started : Stopped :

LITHIUM CARBONATE (Other drug)

Reason :

500 Milligram Daily

Batch : Started : Stopped :

MULTIVITAMINS (Other drug)

Reason :

Batch : Started : Stopped :

OLANZAPINE (Other drug)

Reason :

20 Milligram Daily

Batch : Started : Stopped :

RISPERIDONE (Other drug)

Reason :

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				His investigations revealed a raised white cell count with normal urea, electrolytes and liver function tests. His blood gases showed metabolic acidosis. The abdominal x-ray revealed multiple fluid levels and faecal loading mainly in his large bowel. The computed tomography scan similarly showed that his transverse and descending colon was loaded with faeces until the rectum, with no evidence of a mechanical obstruction. He was diagnosed with sepsis due to faecal impaction. Urgent exploratory laparotomy revealed severely impacted faeces in the large and small bowel.

Public Case Detail

Cases Count: 393

Case Number : 243846

Data Entry Date : 15/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2008

Age :

Outcome : 30/07/2008

DOB : 15/12/1971

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased treatment with Clopine due to myocarditis.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	1 Dose Unspec	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin	<0.03			troponin peaked at 3.20.
Magnetic Resonance Imaging				MRI heart scan consistent with myocarditis and elevated CK.

Public Case Detail

Cases Count: 393

Case Number : 243847

Data Entry Date : 15/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 22/07/2008

Age :

DOB : 03/06/1980

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient ceased treatment with Clopine due to severe neutropenia and severe leucopenia.	Ceased Clopine
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		24/07/2008	2.80	
White blood cells		23/07/2008	2.10	
White blood cells		22/07/2008	1.70	
White blood cells		24/06/2008	3.80	
Neutrophils		24/07/2008	0.80	
Neutrophils		23/07/2008	0.70	
Neutrophils		22/07/2008	0.60	
Neutrophils		24/06/2008	2.40	

Case Number : 243849

Data Entry Date : 15/08/2008
Hospitalisation : Admitted to hospital
Onset Date : 23/06/2008
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 23/12/1969
Causality : Causality certain

Information: CERT (rechall)
 Rechallenged on Clozapine starting on 30/7/08 but developed high grade fever again and Clozapine stopped accordingly.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed high grade fever after commencing on Clozapine. Titrated from 25mg daily up to 350 mg daily from 23/6/08 to 2/7/08.	Clozapine stopped permanently

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
350 Milligram Daily	
Batch :	Started : 23/06/2008 Stopped : 02/07/2008
AMISULPRIDE (Other drug)	Reason :
400 Milligram	
Batch :	Started : Stopped :
EPILIM (Other drug)	Reason : Other&unspecified epilepsy
1000 Milligram Daily	
Batch :	Started : Stopped :
SEROQUEL (Other drug)	Reason : Unspecified schizophrenia
800 Milligram Daily	
Batch :	Started : Stopped :
THYROXINE SODIUM (Other drug)	Reason : Myxedema
100 Milligram Daily	
Batch :	Started : Stopped :

Public Case Detail

Cases Count: 393

Case Number : 244025

Data Entry Date : 21/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/07/2008

Age :

DOB : 10/04/1941

Outcome : 27/07/2008

Causality : Causality possible

Recovered with sequelae

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Leukopenia		Severe reduction in WCC and differentials (agranulocytosis). Resulted in slow recovery.	Ceasation of Clozapine
Agranulocytosis			

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet		1 time	Oral
Batch :	Started :	Stopped : 21/07/2008	0

Public Case Detail

Cases Count: 393

Case Number : 244054

Data Entry Date : 21/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 02/04/2008

Age :

DOB : 15/05/1952

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Somnambulism		sleep walking	dose reduced to 600 mg on 2/4/08 - sleep walking ceased after dose reduction

Medicine details :			
CLOZAPINE (Suspected)	Reason :		
Tablet	700 Milligram	Oral	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 244169

Data Entry Date : 26/08/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/07/1955

Outcome :

Causality : Causality possible

Unknown

Information: The patient's white cell and neutrophil counts were within normal limits for the treatment period

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis.	Clopine ceased.

Medicine details :

CLOPINE (Suspected)	Reason :	
Tablet	175 Milligram	Daily
		Oral
Batch :	Started : 12/06/2008	Stopped : 04/07/2008

Public Case Detail

Cases Count: 393

Case Number : 244218

Data Entry Date : 28/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/08/2008

Age :

DOB : 03/07/1975

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia.	
Hepatitis C			
Lymphocytosis			

Medicine details :			
CLOZARIL (Suspected)		Reason :	
		800 Milligram	Daily
Batch :	Started :	Stopped :	12/08/2008

Public Case Detail

Cases Count: 393

Case Number : 244231

Data Entry Date : 28/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 11/08/2008

Age :

Outcome : 11/08/2008

DOB : 22/02/1970

Death

Causality : Causality possible

Information: Further information received - Medical history: Pt had h/o COPD and polycythaemia. The cause of death was related to underlying disease.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient experienced a myocardial infarction and died whilst being treated with Clopine.	

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 29/05/2006	Stopped : 11/08/2008	
CLOZAPINE (Suspected)		Reason :	
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 19/10/1994	Stopped : 29/05/2006	
RISPERIDONE (Suspected)		Reason : Unspecified schizophrenia	
	1 Milligram	Daily	
Batch :	Started :	Stopped : 09/08/2008	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				The patient's white cell count and neutrophil counts were generally within the normal ranges throughout.

Case Number : 244340

Data Entry Date : 03/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 33Y

Outcome :

DOB :

Recovered

Causality : Causality possible

Information: Floreani J, Bastiampillai T. Successful re-challenge with clozapine following development of clozapine-induced cardiomyopathy. Australian & New Zealand Journal of Psychiatry. Aug 2008, 42 (8): 747-748.
Other: Medically Important: Required Intervention.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Clozapine induced cardiomyopathy	ACE-I, ramipril 5mg, digoxin 250ug, carvedilol

Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia	
Batch :	Started :	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				In December 2004, a routine echo indicated a mildly dilated left ventricle (LV) with mild LV dysfunction and ejection fraction (EF) 45-90%. On cardiology review, the diagnosis was made of probable mild cardiomyopathy. A repeat echocardiogram 6 months later demonstrated a significant worsening of his LV function, with EF 35-40% and increased LV dilatation.

Case Number : 244349

Data Entry Date : 03/09/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/07/2008

Age :

DOB : 14/02/1976

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and leucopenia.	
Leukopenia			

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	700 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		30/06/2008	3.70	
White blood cells		28/07/2008	2.50	
White blood cells		29/07/2008	2.00	
White blood cells		30/07/2008	2.50	
White blood cells		31/07/2008	1.70	
White blood cells		01/08/2008	2.10	
White blood cells		02/08/2008	1.60	
White blood cells		03/08/2008	2.80	
White blood cells		04/08/2008	1.80	
White blood cells		05/08/2008	1.70	
White blood cells		06/08/2008	2.00	
Neutrophils		30/06/2008	2.20	
Neutrophils		28/07/2008	1.10	
Neutrophils		29/07/2008	0.80	
Neutrophils		30/07/2008	1.70	
Neutrophils		31/07/2008	0.80	
Neutrophils		01/08/2008	0.90	
Neutrophils		02/08/2008	0.80	
Neutrophils		03/08/2008	1.20	
Neutrophils		04/08/2008	0.90	
Neutrophils		05/08/2008	0.90	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		06/08/2008	1.20	

Public Case Detail

Cases Count: 393

Case Number : 244350

Data Entry Date : 03/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2008

Age :

Outcome : 18/07/2008

DOB : 25/12/1982

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 20/06/2008	Stopped :	17/07/2008

Public Case Detail

Cases Count: 393

Case Number : 244352

Data Entry Date : 03/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 23/12/1969

Outcome :

Causality : Causality certain

Recovered

Information: Cert(rechall)
Patient recommenced Clopine and developed same symptoms.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient developed rigors, fever up to 41.5 degrees C and felt unwell.	Ceased Clopine
Chills			
Dizziness			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	350 Milligram	Daily	Oral
Batch :	Started :	Stopped :	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				The patient was investigated extensively with blood tests, cultures, X-rays and CT scans with no identified focus of infection.

Public Case Detail

Cases Count: 393

Case Number : 244424

Data Entry Date : 08/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 99U

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Patient experienced increased CK serum.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	550 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/08/2008	895	

Public Case Detail

Cases Count: 393

Case Number : 244425

Data Entry Date : 08/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/08/2008

Age :

DOB : 31/07/1980

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 03/07/2008	Stopped : 12/08/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		08/08/2008	4.60	
White blood cells		12/08/2008	3.10	
White blood cells		15/08/2008	3.10	
Neutrophils		08/08/2008	1.80	
Neutrophils		12/08/2008	0.80	
Neutrophils		15/08/2008	1.20	

Public Case Detail

Cases Count: 393

Case Number : 244453

Data Entry Date : 08/09/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/07/2008

Age :

DOB : 02/04/1968

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Low neutrophil counts and neutropenia.	Ceased clopine

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	600 Milligram Daily Oral
Batch :	Started : 16/03/2007 Stopped : 09/07/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		01/08/2008	4.10	
White blood cells		31/07/2008	2.50	
White blood cells		28/07/2008	5.40	
White blood cells		25/07/2008	2.90	
White blood cells		23/07/2008	4.80	
White blood cells		21/07/2008	3.60	
White blood cells		17/07/2008	2.40	
White blood cells		16/07/2008	3.30	
White blood cells		15/07/2008	3.60	
White blood cells		14/07/2008	5.40	
White blood cells		10/07/2008	4.50	
White blood cells		09/07/2008	4.10	
White blood cells		08/07/2008	5.00	
White blood cells		07/07/2008	3.70	
White blood cells		03/07/2008	4.80	
White blood cells		30/07/2008	4.20	
White blood cells		02/06/2008	6.30	
Neutrophils		01/08/2008	2.00	
Neutrophils		31/07/2008	1.00	
Neutrophils		28/07/2008	1.50	
Neutrophils		25/07/2008	0.90	
Neutrophils		23/07/2008	1.70	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		21/07/2008	1.10	
Neutrophils		17/07/2008	0.90	
Neutrophils		16/07/2008	1.00	
Neutrophils		15/07/2008	1.00	
Neutrophils		14/07/2008	1.50	
Neutrophils		10/07/2008	1.80	
Neutrophils		09/07/2008	1.00	
Neutrophils		08/07/2008	1.90	
Neutrophils		07/07/2008	1.30	
Neutrophils		03/07/2008	1.70	
Neutrophils		30/06/2008	1.50	
Neutrophils		02/06/2008	3.10	

Public Case Detail

Cases Count: 393

Case Number : 244480

Data Entry Date : 08/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2008

Age :

DOB : 02/09/1932

Outcome :

Causality : Causality possible

Unknown

Information: Had previously been on Clozaril with no problems.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Blood creatine phosphokinase increased, neutrophil count decreased.	
Neutrophil count decreased			

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

150 Milligram

Daily

Oral

Batch :

Started :

Stopped :

0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin				Troponin level was 0.3 (unit and normal range not specified) which was reported as normal.
Creatine phosphokinase		15/05/2008	63	Unit & normal range not specified
Creatine phosphokinase		26/07/2008	1257	Unit & normal range not specified
Creatine phosphokinase		28/07/2008	1455	Unit & normal range not specified
Neutrophils				Unit & normal range not specified - 26 - 7.6

Case Number : 244532

Data Entry Date : 10/09/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date :

Age :

DOB : 23/09/1974

Outcome :

Causality : Causality possible

Unknown

Information: patient is an IV drug user and has hepatitis C, recently discharged from jail, and had been receiving methadone until stopping a week prior to event

Reaction :

Preferred Term	Severity	Report Description	Treatment
Faecaloma	Caused or prolonged inpatient hospitalisation	Distended abdomen, faecal impaction, acidosis, tachycardia, suspected overdose and collapsed state.	
Tachycardia	Caused or prolonged inpatient hospitalisation	persistent 120 bpm or higher	
Overdose	Caused or prolonged inpatient hospitalisation	suspected clozapine overdose	
Acidosis	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

400 Milligram Daily

Batch :

Started : 20/12/2007

Stopped : 04/08/2008

0

Public Case Detail

Cases Count: 393

Case Number : 244543

Data Entry Date : 10/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/01/1982

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Increased creatine kinase levels.	

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 04/07/2008	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine kinase MB				Aug - 2008: 625 (>7 times ULN)

Public Case Detail

Cases Count: 393

Case Number : 244544

Data Entry Date : 10/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 17/07/1974

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased clopine

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 29/07/2008	Stopped :	13/08/2008

Public Case Detail

Cases Count: 393

Case Number : 244562

Data Entry Date : 11/09/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 01/03/1942

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion		Because of poor compliance, the patient had stopped Clozaril on 20 Sep 2001 and restarted at full dose abruptly (about 7 to 9 years ago). The patient experienced seizures by stopping Clozaril and restarting at full dose.	
Treatment noncompliance			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Batch :	Started : 03/06/1994	Stopped : 20/09/2001	

Public Case Detail

Cases Count: 393

Case Number : 244976

Data Entry Date : 30/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 31/07/2008

Age :

DOB : 03/03/1941

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Intestinal obstruction		Functional bowel obstruction secondary to constipation.	
Constipation			

Medicine details :			
CLOZARIL (Suspected)		Reason :	
	375 Milligram	Daily	
Batch :	Started : 05/05/2003	Stopped : 31/08/2007	

Public Case Detail

Cases Count: 393

Case Number : 244984

Data Entry Date : 30/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 24/04/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy and reduced ejection fraction	Ceased clopine
Ejection fraction decreased			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 10/01/2007	Stopped : 17/07/2008	

Case Number : 245166

Data Entry Date : 03/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/02/2007

Age :

DOB : 24/05/1948

Outcome : 15/02/2007

Causality : Causality possible

Death

Information: Current Condition: Overweight, hypertensive, smoker.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	The reporter stated that the patient was deceased and that he had died on 15/02/2007. Follow up received from the coroner on 04/09/2008.	
Arrhythmia	Death		
Drug level increased	Death		
Hyperhidrosis	Death		

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	700 Milligram	Daily	Oral
Batch :	Started : 15/02/1996	Stopped :	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason :	
	100 Milligram	Daily	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				Toxicology report revealed high level of clozapine which was capable of being toxic
Serum drug level		19/02/2008	0.5 mg/l	Sertraline level
Serum drug level		19/02/2008	3.9 mg/l	Clozapine level
Serum drug level		19/02/2008	2.9 mg/l	Desmethyl clozapine

Public Case Detail

Cases Count: 393

Case Number : 245270

Data Entry Date : 08/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/08/2008

Age :

DOB : 22/01/1978

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		30 year old male patient experienced a tonic-clonic seizure whilst on Clopine.	He was given midazolam 5 mg intravenous stat and was reviewed by the neurologist. Treatment with Clopine is continuing and he is having a variable dose of lamotrigine.

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	75 Milligram Daily Oral
Batch :	Started : 15/08/2008 Stopped :
ZUCLOPENTHIXOL ACETATE (Suspected)	Reason : Unspecified psychosis
	100 Milligram Daily
Batch :	Started : Stopped :

Case Number : 245272

Data Entry Date : 08/10/2008
Hospitalisation : Admitted to hospital
Onset Date : 15/08/2008
Outcome :
 Not yet recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 10/06/1960
Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	A 48 year old male who ceased Clopine treatment due to experience clozapine induced myocarditis.	Transferred to CCU. Ceased Clopine. Aspirin, Plavix, Metoprolol and Ramipril.
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	125 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
DOCUSATE SODIUM (Other drug)		Reason : Constipation	
	120 Milligram	Daily	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin				1.03
White blood cells				12.6 x 10 ⁹ /L
C-Reactive Protein				186
Chest X-ray				Normal
Electrocardiography				Showed generalised ST elevation and T-wave flattening
Echocardiogram				Showed new mild impairment of left ventricular (LV) function (LVEF ~40%, which was previously normal), with inferior and inferioseptal wall akinesis of LV.

Case Number : 245359

Data Entry Date : 13/10/2008
Hospitalisation : Admitted to hospital
Onset Date : 15/08/2008
Outcome : 28/08/2008
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 04/11/1962
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Experienced possible myocarditis, elevated troponin I, urticarial rash and chest pain.	Ceased Clopine
Chest pain	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		
Urticaria	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
	50 Milligram	Daily	Oral
Batch : 25820/26305	Started : 13/08/2008	Stopped : 27/08/2008	
SODIUM VALPROATE (Other drug)		Reason :	
	2000 Milligram	Daily	
Batch :	Started :	Stopped :	
VITAMIN NOS (Other drug)		Reason :	
	1 Dose Unspec	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Troponin		26/08/2008	0.20 NG/ML	
Troponin		27/08/2008	0.03 NG/ML	
Troponin		28/08/2008	0.02 NG/ML	
Creatine kinase MB		27/08/2008	68	
Creatine kinase MB		28/08/2008	32	
Serum drug level		26/08/2008	66 Microg/L	

Public Case Detail

Cases Count: 393

Case Number : 245364

Data Entry Date : 13/10/2008
Hospitalisation : Admitted to hospital
Onset Date : 26/08/2008
Outcome :
 Recovered

Gender : M
Weight (kg) : 104
Age :
DOB : 04/11/1962
Causality : Causality probable

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pain and urticarial rash	Ceased Clopine, monitored with blood tests
Urticaria	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
75 Milligram Daily	
Batch :	Started : 13/08/2008 Stopped : 27/08/2008
FISH OIL NOS (Other drug)	Reason :
Batch :	Started : Stopped :
MULTIVITAMINS (Other drug)	Reason :
Batch :	Started : Stopped :
SODIUM VALPROATE (Other drug)	Reason :
2 Gram Daily	
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		26/08/2008	0.20	
Troponin		27/08/2008	0.03	
Troponin		28/08/2008	0.02	
Creatinine		27/08/2008	68	
Creatinine		28/08/2008	32	
Serum drug level		26/08/2008	66	

Public Case Detail

Cases Count: 393

Case Number : 245370

Data Entry Date : 13/10/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 24/07/2008

Age :

Outcome : 25/07/2008

DOB : 31/10/1944

Recovered

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation	Caused or prolonged inpatient hospitalisation	Patient experienced cardiac complications.	Ceased Clopine
Syncope	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
	450 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 245399

Data Entry Date : 14/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/08/2008

Age :

DOB : 31/10/1960

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Pneumonia	Ceased Clopine

Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	900 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 245401

Data Entry Date : 14/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 07/05/1965

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient experienced cardiomyopathy.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	700 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Case Number : 245402

Data Entry Date : 14/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2008

Age :

DOB : 13/02/1947

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Syncope	Caused or prolonged inpatient hospitalisation	Patient experienced a fall and fractured her right arm, patient also has a history of lithium toxicity	Ceased Clopine
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 01/01/2002	Stopped : 22/07/2008	
LITHIUM CARBONATE (Suspected)		Reason : Depression	
Tablet	500 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
DOTHIEPIN HYDROCHLORIDE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				Lithium blood level: mildly toxic.

Case Number : 245405

Data Entry Date : 14/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/08/2008

Age :

DOB : 22/04/1952

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced clozapine-induced myocarditis.	Clopine was ceased, dose of ramipril was increased and bisoprolol was started.

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
Batch :	Started : 30/07/2008 Stopped : 19/08/2008
ASPIRIN (Other drug)	Reason :
Tablet	100 Milligram Oral
Batch :	Started : 26/06/2008 Stopped :
RAMIPRIL (Other drug)	Reason :
	1.3 Milligram Daily
Batch :	Started : Stopped :
ZUCLOPENTHIXOL ACETATE (Other drug)	Reason : Unspecified psychosis
	20 Milligram Daily
Batch :	Started : 05/06/2008 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		05/08/2008	0.00	
Troponin		06/08/2008	0.02	
Troponin		12/08/2008	0.00	
Troponin		19/08/2008	0.40	
Troponin		19/08/2008	0.04	
Troponin		20/08/2008	0.00	
Biochemistry				Pre-clozapine:LVEF-35% (known LV impairment prior to clozapine).
Heart Rate				Aug-2008: Heart rate-mild tachycardia of 104 BPM.
Electrocardiography				Aug-2008: ECG-Generalised T-Wave flattening and upward sloping of ST segment.

Public Case Detail

Cases Count: 393

Case Number : 245413

Data Entry Date : 14/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/08/2008

Age :

DOB : 26/12/1958

Outcome :

Causality : Causality possible

Unknown

Information: Request for additional information has been faxed to the patient's treating doctor.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest		Patient commenced treatment with clozapine and switched to the Clopine brand on 19/7/2004. Patient experienced a cardiac arrest.	Ceased Clopine

Medicine details :

CLOPINE (Suspected)	Reason :		
	300 Milligram	Daily	Oral
Batch :	Started : 19/07/2004	Stopped :	17/08/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				Normal
Neutrophils				Normal

Case Number : 245437

Data Entry Date : 14/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/09/2008

Age :

DOB : 07/05/1959

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dysarthria		Patient ceased treatment with Clopine due to slurred speech, tachycardia, throat tightness, excess drooling, being dizzy, abnormal ECG (V1 and V2 T-wave inversion), and elevated creatine kinase.	Ceased Clopine.
Blood creatine phosphokinase increased			
Dizziness			
Drooling			
Electrocardiogram T wave inversion			
Electrocardiogram abnormal			
Tachycardia			
Throat tightness			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
250 Milligram Daily Oral	
Batch :	Started : 18/08/2008 Stopped : 02/09/2008
BECLOMETHASONE DIPROPIONATE (Other drug)	Reason :
200 Microgram	
Batch :	Started : Stopped :
DOCUSATE SODIUM (Other drug)	Reason :
Tablet 2 Dose Unspec	
Batch :	Started : Stopped :
SALBUTAMOL (Other drug)	Reason : Asthma
Inhalation	
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography		01/09/2008	V1 and V2 T-Wave inversion	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		01/09/2008	0.05	
Creatine kinase MB		01/09/2008	852	
Haemoglobin		01/09/2008	112	

Case Number : 245439

Data Entry Date : 14/10/2008
Hospitalisation : Admitted to hospital
Onset Date : 17/09/2008
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 01/03/1974
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient developed fever, and later in the day had a grand mal seizure. Patient had also developed Neuroleptic malignant syndrome on an unknown date and symptoms of fever and cardiovascular instability persisted for some days and creatine kinase peaked at 13000	Ceased ziprasidone. Treated with bromocriptine
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Cardiovascular insufficiency	Caused or prolonged inpatient hospitalisation		
Grand mal convulsion	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZAPINE (Suspected)	Reason :		
Batch :	Started :	Stopped :	
Lexapro (Suspected)	Reason : Depression		
	10 Milligram	Daily	Oral
Batch :	Started : 30/03/2008	Stopped :	
PERIACTIN (Suspected)	Reason :		
	4 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
Zeldox (Suspected)	Reason : Unspecified schizophrenia		
Capsule	160 Milligram	Daily	Oral
Batch :	Started : 17/07/2008	Stopped :	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	<200	29/09/2008	13000	
Creatine phosphokinase	<200	22/09/2008	4000	
Creatine phosphokinase	<200	29/09/2008	164	

Public Case Detail

Cases Count: 393

Case Number : 245539

Data Entry Date : 16/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2008

Age :

DOB : 18/03/1983

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Hirsutism		Patient has noticed an increase in facial hair growth and has gained alot of weight, about 10 to 20kg.	Sodium valproate discontinued for a year.
Weight increased			

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	450 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped : Continuing.
SODIUM VALPROATE (Suspected)		Reason : Manic-depression psycho,manic	
Tablet	1 Gram	Daily	Oral
Batch :	Started : 15/04/2008	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 245580

Data Entry Date : 20/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 27/08/2008

Age :

DOB : 26/02/1971

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Hypotension		Patient experienced severe hypotension.	Clozaril ceased.

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	25 Milligram	Daily	Oral
Batch :	Started : 13/08/2008	Stopped :	27/08/2008

Case Number : 245583

Data Entry Date : 20/10/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 25/06/2008

Age :

DOB : 10/01/1974

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Heaviness in chest, elevated creatine kinase, shortness of breath and palpitations.	
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Haematocrit decreased	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		
Red blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)

Reason :

Tablet 325 Milligram Daily Oral

Batch : Started : 03/06/2008 Stopped :

ANTIDEPRESSANT NOS (Other drug)

Reason :

Batch : Started : Stopped :

EFEXOR-XR (Other drug)

Reason :

300 Milligram

Batch : Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		25/06/2008	266 IU/l	
Creatine phosphokinase		01/09/2008	970 IU/l	
Creatine phosphokinase		02/09/2008	622 IU/l	
Creatine phosphokinase		02/09/2008	626 IU/l	
Creatine phosphokinase		04/09/2008	355	
Creatine phosphokinase		05/09/2008	335	
Haematocrit		01/09/2008	0.39 L/L	
Lymphocytes		25/06/2008	0.4 x 10 ⁹ /L	
Red blood cells		25/06/2008	4.31 x 10 ¹² /L	
Red blood cells		01/09/2008	4.24 x 10 ¹² /L	
Echocardiogram				04/09/2008: Trivial circumferential pericardial effusion.

Public Case Detail

Cases Count: 393

Case Number : 245631

Data Entry Date : 20/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 31/08/2008

Age :

DOB : 01/06/1962

Outcome :

Causality : Causality probable

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	unwell, tiredness, lethargy, poor appetite and diarrhoea, increased temperature	ceased clopine

Medicine details :			
CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
	200 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
ATORVASTATIN (Other drug)		Reason :	
	20 Milligram		Oral
Batch :	Started :	Stopped :	
FLUOXETINE HYDROCHLORIDE (Other drug)		Reason :	
	20 Milligram		Oral
Batch :	Started :	Stopped :	
PANTOPRAZOLE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Haematology				elevated Tropin I, creatine kinase, white blood cells, neutrophils and eosinophils.

Public Case Detail

Cases Count: 393

Case Number : 245640

Data Entry Date : 20/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/04/1973

Outcome :

Causality : Causality probable

Unknown

Information: Patient commenced treatment with Clopine and was stable on 550mg po daily for several years prior to event. Patient was recommenced with Clopine on 11/9/08 and at time of report, did not have a recurrence of neutropenia.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		thrombocytopenia with platelet count of 46. Experienced moderate neutropenia.	Ceased Clopine
Neutropenia			

Medicine details :

CLOPINE (Suspected)	Reason :
	50 Milligram Daily Oral
Batch :	Started : 16/03/2005 Stopped : 05/09/2008

Case Number : 245645

Data Entry Date : 20/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 11/09/2008

Age :

DOB : 25/07/1978

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		severe neutropenia	

Medicine details :

CLOPINE (Suspected)

Reason :

300 Milligram

Daily

Oral

Batch :

Started : 27/09/2006

Stopped : 11/09/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		23/07/2008	5.90	
White blood cells		14/08/2008	4.90	
White blood cells		11/09/2008	3.70	
White blood cells		12/08/2008	4.00	
White blood cells		13/09/2008	4.60	
White blood cells		18/09/2008	4.70	
Neutrophils		23/07/2008	2.70	
Neutrophils		14/08/2008	1.70	
Neutrophils		11/09/2008	0.90	
Neutrophils		12/08/2008	1.50	
Neutrophils		13/09/2008	1.70	
Neutrophils		18/09/2008	1.90	

Public Case Detail

Cases Count: 393

Case Number : 245646

Data Entry Date : 20/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/03/2008

Age :

DOB : 25/07/1971

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pericarditis		Pericarditis	

Medicine details :			
CLOPINE (Suspected)	Reason : Unspecified schizophrenia		
	125 Milligram	Daily	Oral
Batch :	Started : 03/03/2008	Stopped : 19/03/2008	0

Case Number : 245715

Data Entry Date : 21/10/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 22/08/2008

Age :

DOB : 29/09/1972

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count increased	Caused or prolonged inpatient hospitalisation	Raised white blood cells, eosinophilia, raised neutrophil count, elevated platelets and elevated monocytes.	
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Monocyte count increased	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Platelet count increased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

350 Milligram

Daily

Oral

Batch :

Started : 25/07/2008

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		22/08/2008	16.20 x 10 ⁹ /L	
White blood cells		15/08/2008	9.60 x 10 ⁹ /L	
White blood cells		07/08/2008	9.70 x 10 ⁹ /L	
Neutrophils		22/08/2008	10.80 x 10 ⁹ /L	
Neutrophils		15/08/2008	6.40 x 10 ⁹ /L	
Neutrophils		07/08/2008	5.40 x 10 ⁹ /L	
Eosinophils		22/08/2008	1.3	
Platelets		22/08/2008	473	
Monocytes		22/08/2008	1.3	

Public Case Detail

Cases Count: 393

Case Number : 245775

Data Entry Date : 23/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/08/2008

Age :

DOB : 25/03/1976

Outcome :

Causality : Causality possible

Death

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Death	Patient died due to a perforated bowel whilst being treated with Clopine 400mg.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Neutrophils				The patient's neutrophil counts were within normal ranges.
White blood cells				Patient's white cell counts were within normal ranges for the treatment period.

Public Case Detail

Cases Count: 393

Case Number : 245889

Data Entry Date : 29/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 27/09/2008

Age :

DOB : 29/06/1978

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Patient experienced arrhythmia, hypersalivation and tiredness.	
Fatigue			
Salivary hypersecretion			

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	12.5 Milligram	Daily	Oral
Batch :	Started : 27/08/2008	Stopped :	17/09/2008

Case Number : 245975

Data Entry Date : 05/11/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 05/04/1983

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Patient developed pneumonia and QT interval prolonged. Sinus tachycardia and left atrial enlargement.	
Electrocardiogram QT interval			
Left atrial dilatation			
Sinus tachycardia			

Medicine details :

CLOPINE (Suspected)	Reason :		
	650 Milligram	Daily	Oral
Batch :	Started : 24/11/2008	Stopped :	
FLUTICASONE PROPIONATE-SALMETEROL XINAFOATE (Otl	Reason :		
Inhalation			Inhalation
Batch :	Started :	Stopped :	
LAMOTRIGINE (Other drug)	Reason :		
	200 Milligram		
Batch :	Started :	Stopped :	
VENLAFAXINE HYDROCHLORIDE (Other drug)	Reason :		
	300 Milligram		
Batch :	Started :	Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				13/09/2008: Prolonged QTC interval (508 MS), sinus tachycardia, left atrial enlargement, non-specific T widespread abnormalities. 23/06/2008: QTC interval 437 MS. 13/12/2007: QTC interval 481 MS.

Public Case Detail

Cases Count: 393

Case Number : 245990

Data Entry Date : 05/11/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 24/09/2008

Age :

DOB : 21/10/1987

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed a fever of 39.4c.	Clozaril discontinued.
Neutropenia	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	150 Milligram	Daily	Oral
Batch :	Started : 14/09/2008	Stopped : 30/09/2008	0

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils	7.7-1.6	30/09/2008	0.90x10 ⁹ /L	
Neutrophils	7.7-1.6	01/10/2008	3.0x10 ⁹ /L	
White blood cells	11.0-4.5	30/09/2008	2.80x10 ⁹ /L	
White blood cells	11.0-4.5	01/10/2008	5.8x10 ⁹ /L	

Public Case Detail

Cases Count: 393

Case Number : 245996

Data Entry Date : 05/11/2008
Hospitalisation : Admitted to hospital
Onset Date : 12/09/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 18/03/1983
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Troponin increased	Caused or prolonged inpatient hospitalisation	Patient experienced elevated troponin, persistent low grade fever, mild neutrophilia, moderate monocytosis and pharyngitis.	
Monocytosis	Caused or prolonged inpatient hospitalisation		
Neutrophilia	Caused or prolonged inpatient hospitalisation		
Pharyngitis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	87.5 Milligram	Daily	Oral
Batch :	Started : 29/08/2008	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Neutrophils	1.8 - 7.7 x 10 ⁹ /L	17/09/2008	8.7 x 10 ⁹ /L	
White blood cells	4.5 - 11.0 x 10 ⁹ /L	17/09/2008	12.10 x 10 ⁹ /L	

Case Number : 246001

Data Entry Date : 05/11/2008
Hospitalisation : Admitted to hospital
Onset Date : 04/04/2008
Outcome :
 Recovered

Gender : F
Weight (kg) : 137
Age :
DOB : 13/12/1978
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced pain in her leg, pain in her chest and weight gain. Patient collapsed and was taken to hospital, she was found to have a pulmonary embolism.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Pain in extremity	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	400 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Other data				4/4/08: Scan showed significant emboli.

Case Number : 246112

Data Entry Date : 10/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/09/1950

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular hypokinesia		The patient with a history of hypertension and smoking, had an echocardiogram which revealed left atrial enlargement, a normal left ventricular size and function but a sigmoid shaped septum and a marked difference in the left ventricular shortening in comparison to the last year's echocardiogram which was not commented upon previously. Prior to this another echocardiogram performed on 10/08/08 noted sinus tachycardia and a atrial right bundle branch block. No such events were reported in echocardiograms performed on 02/08/08 and 21/06/08.	
Bundle branch block right			
Sinus tachycardia			
Tachycardia			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
Batch :	Started :
Stopped :	
VENLAFAXINE HYDROCHLORIDE (Suspected)	Reason :
	225 Milligram Daily
Batch :	Started :
Stopped :	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		21/06/2006	Normal size and function	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		02/08/2007	Normal left ventricular systolic function, normal valve function	
Echocardiogram		10/08/2008	Sinus tachycardia and partial RBBB	
Echocardiogram		08/10/2008	Marked difference in the left ventricular shortening in comparison to last year echocardiogram. Right ventricular systolic pressure 35mmHg.	



Public Case Detail

Cases Count: 393

Case Number : 246184

Data Entry Date : 12/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 15/10/1965

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular		Mildly dilated left ventricle, left ventricular hypertrophy, left atrial dilatation/left atrium enlargement, mildly dilated aortic root.	
Aortic dilatation			
Left atrial dilatation			
Left ventricular hypertrophy			

Medicine details :

CLOZARIL (Suspected)	Reason :
	1 Dose Unspec Daily
Batch :	Started :
	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 246192

Data Entry Date : 12/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/09/2008

Age :

DOB : 13/02/1970

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Suspected myocarditis.	Ceased clopine
Cardiac enzymes increased			
Pyrexia			
Tachycardia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	500 Milligram Daily Oral
Batch :	Started : 03/09/2008 Stopped : 19/09/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		27/08/2008	0.02 MCG/L	
Troponin		18/09/2008	0.09 MCG/L	
Troponin		19/09/2008	0.50 MCG/L	
Creatine kinase MB		27/08/2008	538 U/L	
Creatine kinase MB		19/09/2008	1280 U/L	
Other data		21/09/2008	100 beats per minute	

Public Case Detail

Cases Count: 393

Case Number : 246313

Data Entry Date : 17/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/08/1948

Outcome : 09/10/2008

Causality : Causality possible

Death, maybe drug

Information: No past medical history or concomitant medications. Suspected heart attack (myocardial infarction). The patient's white cell and neutrophil counts were within normal ranges for the treatment period. Fatal report.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	60 year old male patient who experienced renal issues and arrhythmias and died due to unknown reasons (suspected heart attack) whilst being treated with Clopine.	
Arrhythmia	Death		
Renal disorder	Death		

Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

100 Milligram

Daily

Oral

Batch :

Started : 08/07/2008

Stopped : 09/10/2008

Case Number : 246411

Data Entry Date : 19/11/2008
Hospitalisation : Admitted to hospital
Onset Date : 15/09/2008
Outcome :
 Not yet recovered

Gender : F
Weight (kg) : 0
Age :
DOB : 30/10/1972
Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Stopped smoking and found elevated LFTs, decreased platelet count, clozapine toxicity with elevated clozapine plasma levels, excess sedation	Clopine stopped;
Drug toxicity			
Sedation			
Thrombocytopenia			

Medicine details :

CLOPINE (Suspected)	Reason :			
	650 Milligram	Daily		
Batch :	Started : 30/08/2008	Stopped : 10/10/2008		
CLOPINE (Suspected)	Reason : Unspecified schizophrenia			
	800 Milligram	Daily	Oral	
Batch :	Started : 29/04/2008	Stopped : 29/08/2008	0	
AMISULPRIDE (Other drug)	Reason :			
	600 Milligram	Daily		
Batch :	Started :	Stopped :	0	
CITALOPRAM HYDROBROMIDE (Other drug)	Reason :			
Batch :	Started :	Stopped :		
EPILIM (Other drug)	Reason : Unspecified schizophrenia			
	2 Gram	Daily		
Batch :	Started :	Stopped :	0	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		09/10/2008	2.9	Clozapine

Public Case Detail

Cases Count: 393

Case Number : 246456

Data Entry Date : 21/11/2008

Hospitalisation :

Onset Date : 07/10/2008

Outcome :

Not yet recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 02/04/1978

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Ceased Clopine
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	550 Milligram	Daily	Oral
Batch :	Started : 18/06/2008	Stopped : 07/10/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		30/09/2008	3.60	
White blood cells		07/10/2008	2.30	
Neutrophils		30/09/2008	2.20	
Neutrophils		07/10/2008	0.80	

Public Case Detail

Cases Count: 393

Case Number : 246546

Data Entry Date : 25/11/2008
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 06/08/1960
Causality : Causality possible

Information: The patient's white cell and neutrophil counts were within normal ranges throughout treatment.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The case of a 48 year old male who experienced a grand mal seizure and hyponatraemia whilst on Clopine.	
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

Medicine details :

ATACAND (Suspected)		Reason :	
Batch :	Started :	Stopped :	
CLOPINE (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 14/10/2003	L TERM	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 246548

Data Entry Date : 25/11/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/10/2008

Age :

DOB : 18/09/1944

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Respiratory disorder	Caused or prolonged inpatient hospitalisation	Patient experienced coronary obstructive respiratory disease, pneumonia and tertiary syphilis.	
Tertiary syphilis	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	450 Milligram	Daily	Oral
Batch :	Started : 30/08/2004	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 246572

Data Entry Date : 25/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/07/2008

Age :

Outcome : 26/07/2008

DOB : 23/08/1980

Death

Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Depression	Death	Patient overdosed on medications available, led to patient being comatose and could not be resuscitated, patient was hospitalised on 26/07/08, died on the 26/07/08, patient had recently developed some depression symptoms, fluctuating paranoid thoughts while under stress.	
Coma	Death		
Completed suicide	Death		
Intentional overdose	Death		
Paranoia	Death		
Stress	Death		

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 12/04/2000	Stopped :	
QUETIAPINE (Suspected)		Reason :	
Batch :	Started :	Stopped :	
SERTRALINE HYDROCHLORIDE (Suspected)		Reason :	
Batch :	Started : 22/04/2008	Stopped :	

Case Number : 246590

Data Entry Date : 25/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 08/09/1958

Outcome :

Causality : Causality possible

Unknown

Information: History: psychosis, hypothyroidism, TSH decreased, hypertension and affective disorder.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood potassium		Blood potassium increased, left ventricular hypertrophy, echocardiogram abnormal, drug level above therapeutic and blood thyroid stimulating hormone decreased.	
Blood thyroid stimulating hormone decreased			
Drug level above therapeutic			
Echocardiogram abnormal			
Left ventricular hypertrophy			

Medicine details :

CLOZARIL (Suspected)	Reason :
625 Milligram Daily	
Batch :	Started :
	Stopped :
LITHIUM CARBONATE (Other drug)	Reason :
Batch :	Started : 19/08/2008
	Stopped :
SODIUM VALPROATE (Other drug)	Reason :
Batch :	Started :
	Stopped :
THYROXINE SODIUM (Other drug)	Reason :
Batch :	Started :
	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood culture	5.3 - 3.7	25/08/2008	5.5	Blood potassium high:
Echocardiogram				26/09/08: Significant mild concentric left ventricular hypertrophy.

Public Case Detail

Cases Count: 393

Case Number : 246591

Data Entry Date : 25/11/2008
Hospitalisation : Admitted to hospital
Onset Date : 21/10/2008
Outcome :
 Unknown

Gender : F
Weight (kg) : 0
Age :
DOB : 23/06/1947
Causality : Causality possible

Information: Concurrent condition of chronic paranoid schizophrenia.

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a possible seizure.	Treated with Epilim

Medicine details :			
CLOZARIL (Suspected)		Reason :	
Tablet	650 Milligram	Daily	Oral
Batch :	Started : 15/05/1957	L TERM	Stopped :

Case Number : 246649

Data Entry Date : 26/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2008

Age :

DOB : 20/09/1975

Outcome :

Causality : Causality possible

Unknown

Information: The patient has a past medical history on ECG of sinus rythym (30/03/06), sinus tachycardia (118 bpm) and QTc interval of 511 msec (06/07/06), and sinus tachycardia of 118 bpm and a t-wave inversion infero-laterally (consider ischaemia) (16/07/06). Previous echocardiograms were generally normal (30/06/06, 08/03/07 and 10/10/07).

Reaction :

Preferred Term	Severity	Report Description	Treatment
ECG signs of myocardial ischaemia			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	550 Milligram Daily Oral
Batch :	Started : 24/05/2006 Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography		30/03/2006	Sinus rythym, otherwise normal	
Electrocardiography		05/04/2006	QTc Interval = 383 msec	
Electrocardiography		23/06/2006	QTc Interval = 504 msec, Sinus Tachycardia (118 BPM)	
Electrocardiography		06/07/2006	QTc Interval = 511 msec, Sinus Tachycardia (120 BPM)	
Electrocardiography		16/07/2006	QTc Interval = 502 msec, Sinus Tachycardia (118 BPM), T-Wave inversion infero-laterally (possibly ischaemia)	
Electrocardiography		10/10/2007	QTc Interval = 406 msec	
Electrocardiography		15/09/2008	QTc Interval = 435 msec, Sinus Rythym (93 BPM), Possible Inferior Infarct, age undeterminant	
Echocardiogram		30/06/2006	Normal Study	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		15/09/2008	Elevated sinus rate (87-93 BPM), Normal LV size and systolic function, Estimated ejection fraction of 65%, Normal Valvular function.	

Public Case Detail

Cases Count: 393

Case Number : 246665

Data Entry Date : 27/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2008

Age :

DOB : 11/11/1982

Outcome : 10/08/2008

Causality : Causality possible

Recovered

Information: Patient's white blood cell counts and neutrophil counts were within normal ranges for the treatment period.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Patient developed early myocarditis, palpitations, shortness of breath, dizziness, chest tightness and significant postural drops.	Clopine was ceased.
Blood creatine phosphokinase increased	Life threatening		
Blood pressure orthostatic decreased	Life threatening		
Chest discomfort	Life threatening		
Dizziness	Life threatening		
Dyspnoea	Life threatening		
Myocarditis	Life threatening		
Palpitations	Life threatening		

Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	375 Milligram	Daily	Oral
Batch :	Started : 16/08/2008	Stopped : 03/10/2008	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/09/2008	11168	
Echocardiogram				Echocardiogram showed mild left ventricular/right ventricular dysfunction and left ventricular ejection fraction of 50%.
Troponin				09/08 Troponin 1 Normal

Public Case Detail

Cases Count: 393

Case Number : 246812

Data Entry Date : 04/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/10/1972

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug level increased		Patient experienced liver function tests and increased clozapine levels.	Clopine ceased.
Hepatic function abnormal			

Medicine details :			
CLOPINE (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
EPILIM (Suspected)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 246822

Data Entry Date : 04/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 107

Onset Date : 20/07/2008

Age :

DOB : 14/03/1969

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia, white blood cell count decreased, eosinophilia, skin rash.	
Eosinophilia			
Rash			
White blood cell count decreased			

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
Batch :	Started : 15/07/2008		Stopped : 14/10/2008
QUETIAPINE (Other drug)		Reason :	
Batch :	Started :		Stopped :
RISPERIDONE (Other drug)		Reason :	
Batch :	Started :		Stopped :
SODIUM VALPROATE (Other drug)		Reason :	
Batch :	Started :		Stopped :

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Neutrophils	1.8 - 7.7	14/10/2008	1.40	
Neutrophils	1.8 - 7.7	14/10/2008	1.50	
Neutrophils	1.8 - 7.7	31/10/2008	2.7	
Neutrophils	1.8 - 7.7	20/11/2008	1.5	
White blood cells	4.5 - 11.0	23/09/2008	-	
White blood cells	4.5 - 11.0	14/10/2008	3.40	
White blood cells	4.5 - 11.0	14/10/2008	3.90	
White blood cells	4.5 - 11.0	20/11/2008	4.30	

Case Number : 246875

Data Entry Date : 08/12/2008
Hospitalisation : Admitted to hospital
Onset Date : 15/10/2008
Outcome :
 Recovered

Gender : M
Weight (kg) : 0
Age :
DOB : 27/05/1961
Causality : Causality possible

Information:

Reaction :	Severity	Report Description	Treatment
Renal impairment	Caused or prolonged inpatient hospitalisation	Patient who initiated Revlimid on alternate days 1-21, experienced renal impairment, extrapyramidal side effects, myoclonic body movements and suspected drug interaction.	Revlimid was stopped and Clozapine dose ws reduced to 150mg daily.
Drug interaction	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZAPINE (Interaction)	Reason :		
	450 Milligram	Daily	Oral
Batch :	Started : 15/10/2008	Stopped :	
Revlimid (Interaction)	Reason : Multiple myeloma		
	15 Milligram	Daily	Oral
Batch :	Started : 30/09/2008	Stopped : 15/10/2008	0

Public Case Detail

Cases Count: 393

Case Number : 246876

Data Entry Date : 08/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/11/2008

Age :

DOB : 25/11/1963

Outcome :

Causality : Causality probable

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient experienced myocarditis and eosinophilia.	Ceased clozaril
Eosinophilia			

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	250 Milligram	Daily	Oral
Batch :	Started : 07/10/2008	Stopped : 01/11/2008	

Public Case Detail

Cases Count: 393

Case Number : 246880

Data Entry Date : 08/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 74.9

Onset Date :

Age :

DOB : 26/03/1963

Outcome :

Causality : Causality possible

Unknown

Information: Patient's history: Patient has a history of alcohol abuse and stopped drinking alcohol for a period of time, but now drinks 1 to 2 drinks every second day (has done so for the last 2 years). The consultant cardiologist at the hospital reviewed the echocardiogram performed on 09/03/08 with the original echocardiogram and thought it looked unchanged, therefore unlikely to be cardiomyopathy. Patient has had consistently elevated blood pressure since first recorded when starting clozapine, and it has been in the vicinity of 140-150/85-100. He has had tachycardia since starting clozapine. His most recent observations were blood pressure 140/94, heart rate 120bpm, weight 74.9kg and BMI 26. He has had tachycardia since starting clozapine.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal		Patient experienced possible cardiomyopathy, abnormal echo, tachycardia, elevated blood pressure and chest discomfort whilst on Clopine.	Treatment with Clopine was titrated up to a maximum dose of 425mg daily. (100mg mane and 325mg nocte).
Cardiomyopathy			
Hypertension			
Tachycardia			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
425 Milligram	Daily
	Oral
Batch :	Started : 26/03/2007
	Stopped : Continuing.

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		23/09/2008	Normal	
White blood cells		21/10/2008	Normal	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				<p>Just prior to starting clozapine, the patient had normal troponin, UEC and LFT. His ECG showed left axis deviation, with minor St changes. A echocardiogram performed on 11/05/07 was reported as normal (normal left ventricular size and systolic function). On the 12/02/08 the patient has an ECG which showed sinus tachycardia, leftward axis and minor St changes. An echocardiogram performed on 22/02/08 showed normal left ventricular size with normal wall thickness and mild global hypokinesis. Grade I/IV left ventricular diastolic dysfunction, and mild left and right atrial enlargement. On 06/03/08, patient reported discomfort, which was clinically evaluated as unlikely to be cardiogenic. An echocardiogram was performed on 09/03/08 which revealed mild to moderate left ventricular hypertrophy with normal left ventricular function. An echocardiogram performed on 22/03/08 reported changes consistent with cardiomyopathy. An echocardiogram on 09/07/08 showed mildly reduced left ventricular contractility suggesting mild cardiomyopathy, normal left ventricular diastolic filling pressure and no significant functional valvular abnormalities. An ECG on 29/07/08, once again showed sinus tachycardia and minor ST changes, and also showed QTc prolongation. A recent follow-up echocardiogram was performed on 08/10/08, and was reported as mildly reduced left ventricular contractility, suggesting mild cardiomyopathy.</p>

Public Case Detail

Cases Count: 393

Case Number : 246953

Data Entry Date : 09/12/2008
Hospitalisation : Admitted to hospital
Onset Date :
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 25/11/1979
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Gastroenteritis	Caused or prolonged inpatient hospitalisation	Experienced severe gastro whilst being treated with Clopine.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
	150 Milligram	Daily	Oral
Batch :	Started : 22/10/2008	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 247197

Data Entry Date : 16/12/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 31/10/2008

Age :

DOB : 23/08/1982

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia.	Clopine ceased
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	600 Milligram	Daily	Oral
Batch :	Started : 11/03/2008	Stopped : 31/10/2008	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		05/11/2008	13.00	x 10 ⁹ /L
White blood cells		02/11/2008	3.30	x 10 ⁹ /L
White blood cells		01/11/2008	4.00	x 10 ⁹ /L
White blood cells		31/10/2008	2.70	x 10 ⁹ /L
White blood cells		30/10/2008	5.10	x 10 ⁹ /L
Neutrophils		05/11/2008	9.30	x 10 ⁹ /L
Neutrophils		02/11/2008	0.70	x 10 ⁹ /L
Neutrophils		01/11/2008	1.60	x 10 ⁹ /L
Neutrophils		31/10/2008	0.80	x 10 ⁹ /L
Neutrophils		30/10/2008	3.00	x 10 ⁹ /L

Public Case Detail

Cases Count: 393

Case Number : 247198

Data Entry Date : 16/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 17/04/1986

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug level decreased		Switched from Clopine tablet to Clopine suspension and experienced reduced clozapine plasma levels.	

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified psychosis
	900 Milligram Oral
Batch :	Started :
	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		22/05/2006	299 - 116 - 500mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		04/09/2006	363 - 138 - 550mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		08/02/2007	328 - 108 - 550mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		21/04/2008	147 - 82 - 400mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		11/08/2008	186 - 92 - 400mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		25/08/2008	324 - 131 - 700mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		11/09/2008	480 - 160 - 850mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		29/09/2008	268 - 111 - 900mg - Clopine Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		05/11/2008	588 - 206 - 900mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form

Public Case Detail

Cases Count: 393

Case Number : 247199

Data Entry Date : 16/12/2008

Gender : U

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/10/2008

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug level decreased		Patient who was switched from Clopine tablets to Clopine suspension and experienced reduced clozapine plasma levels.	

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified psychosis
Batch :	Started : 600 Milligram Daily Oral
	Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		17/09/2008	415 - 600mg - Clopine Tabs	Clozapine - Dose - Form
Serum drug level		01/10/2008	278 - 650mg - Clopine Tabs	Clozapine - Dose - Form
Serum drug level		15/10/2008	235 - 700mg - Clopine suspension	Clozapine - Dose - Form

Public Case Detail

Cases Count: 393

Case Number : 247210

Data Entry Date : 17/12/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 28/01/1974

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction, ejection fraction decreased, lymphocytosis, neutrophilia, neuroleptic malignant syndrome, sinus tachycardia, hypertension, blood cholesterol increased, blood triglycerides increased. Blood glucose increased, treatment noncompliance.	
Blood cholesterol increased			
Blood glucose increased			
Blood triglycerides increased			
Ejection fraction decreased			
Hypertension			
Lymphocytosis			
Neuroleptic malignant syndrome			
Neutrophilia			
Sinus tachycardia			
Treatment noncompliance			

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
Batch :	Started : 15/02/2008 Stopped : 15/10/2008
SEROQUEL (Suspected)	Reason :
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Cholesterol				Blood cholesterol high 7.1.
Serum glucose				Blood glucose high 5.7

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood pressure				140/90 Usal blood pressure.
Triglyceride				High 6.8
Echocardiogram				29/03/2005 Low normal LV contraction with impaired relaxation. 02/06/2008 Mild global LV systolic dysfunction.
Heart Rate				115 high Patient normal ranged 88bpm-112bpm.

Public Case Detail

Cases Count: 393

Case Number : 247239

Data Entry Date : 18/12/2008

Gender : U

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/10/2008

Age : 99u

Outcome :

DOB :

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug level decreased		Switched from Clopine tablets to Clopine suspension and experienced reduced clozapine plasma levels.	

Medicine details :

CLOPINE (Suspected)	Reason : Unspecified psychosis
	600 Milligram Daily Oral
Batch :	Started : Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		28/05/2008	392; 600mg; Clopine Tabs	Clopine Plasma Levels, Dose, Form
Serum drug level		17/09/2008	820; 700mg; Macquarie Suspension	Clopine Plasma Levels, Dose, Form
Serum drug level		15/10/2008	362; 700mg; Clopine Suspension	Clopine Plasma Levels, Dose, Form

Case Number : 247457

Data Entry Date : 05/01/2009
Hospitalisation : Admitted to hospital
Onset Date : 08/10/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 05/09/1985
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Presented with an overdose and experienced tachycardia, shortness of breath and postural hypotension.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOZARIL (Suspected)	Reason :		
Tablet	100 Milligram	Daily	Oral
Batch :	Started : 26/04/2007	Stopped : 21/09/2008	0

Case Number : 247513

Data Entry Date : 07/01/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/10/2008

Age :

DOB : 20/03/1967

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine and chemotherapy.	
Agranulocytosis			

Medicine details :

Chemotherapy NOS (Suspected)

Reason :

Batch :

Started :

Stopped :

CLOPINE (Suspected)

Reason :

Tablet

450 Milligram

Daily

Oral

Batch :

Started : 15/05/2002

Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		08/10/2008	2.10	
White blood cells		09/10/2008	2.10	
White blood cells		10/10/2008	2.20	
White blood cells		11/10/2008	2.40	
White blood cells		12/10/2008	2.40	
White blood cells		13/10/2008	3.10	
Neutrophils		08/10/2008	0.20	
Neutrophils		09/10/2008	0.10	
Neutrophils		10/10/2008	0.20	
Neutrophils		11/10/2008	0.30	
Neutrophils		12/10/2008	0.40	
Neutrophils		13/10/2008	0.20	

Case Number : 247515

Data Entry Date : 07/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 30/10/1972

Unknown

Causality : Causality possible

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Antipsychotic drug level increased	Caused or prolonged inpatient hospitalisation	Patient experienced elevated LFT's and clozapine plasma levels.	Ceased Clopine
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

Medicine details :

CITALOPRAM HYDROBROMIDE (Suspected)	Reason :
Batch :	Started :
	Stopped :
CLOPINE (Suspected)	Reason :
Tablet	800 Milligram Daily
Batch :	Started :
	Stopped :
EPILIM (Suspected)	Reason :
Batch :	Started :
	Stopped :

Public Case Detail

Cases Count: 393

Case Number : 247563

Data Entry Date : 09/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2008

Age :

DOB : 31/05/1977

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Drug eruption	Caused or prolonged inpatient hospitalisation	Patient experienced skin eruptions (ecrematous plaques on trunk, limbs and face, severe generalised purpuric rash with associated eosinophilial	Clopine ceased
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Purpura	Caused or prolonged inpatient hospitalisation		

Medicine details :			
CLOPINE (Suspected)			
Tablet	200 Milligram	Daily	Oral
Batch :	Started : 15/09/2008	Stopped : 27/09/2008	
RISPERIDONE (Other drug)			
Reason : Unspecified schizophrenia			
Batch :	Started :	Stopped :	
SODIUM VALPROATE (Other drug)			
Reason : Unspecified schizophrenia			
	1 Gram	Daily	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 247612

Data Entry Date : 12/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/11/2008

Age :

DOB : 15/08/1985

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Clozapine induced myocarditis. Developed tachycardia, troponin rise, diarrhoea, postural hypotension, sweating, pale and lethargic. ECG flattened T waves.	

Medicine details :

CLOZAPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	125 Milligram	Daily	Oral
Batch :	Started : 30/10/2008	Stopped : 19/11/2008	

Public Case Detail

Cases Count: 393

Case Number : 247640

Data Entry Date : 12/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 31/10/2008

Age :

DOB : 03/05/1973

Outcome :

Causality : Causality possible

Unknown

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	Clozapine ceased. Peridopril commenced and changed to risperidone.

Medicine details :			
CLOZAPINE (Suspected)		Reason :	
Tablet	325 Milligram	1 time	Oral
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 247705

Data Entry Date : 14/01/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/10/2008

Age :

DOB : 16/03/1949

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced severe neutropenia and severe leucopenia whilst being treated with Clopine.	Clopine ceased.
Agranulocytosis			

Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	400 Milligram Daily Oral
Batch :	Started : 12/08/2008 Stopped : 17/10/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		22/10/2008	0.83	
White blood cells		21/10/2008	0.79	
White blood cells		20/10/2008	1.00	
White blood cells		19/10/2008	1.15	
White blood cells		18/10/2008	1.84	
White blood cells		17/10/2008	1.85	
White blood cells		13/10/2008	3.30	
White blood cells		07/10/2008	4.29	
Neutrophils		22/10/2008	0.01	
Neutrophils		21/10/2008	0.01	
Neutrophils		20/10/2008	0.07	
Neutrophils		19/10/2008	0.32	
Neutrophils		18/10/2008	0.50	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		17/10/2008	0.71	
Neutrophils		13/10/2008	1.60	
Neutrophils		07/10/2008	2.53	

Case Number : 247706

Data Entry Date : 14/01/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 16/10/2008

Age :

DOB : 06/11/1980

Outcome : 22/10/2008

Causality : Causality possible

Recovered

Information:

Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Clopine ceased.
Leukopenia			

Medicine details :

CLOPINE (Suspected)	Reason :	
Tablet	300 Milligram Daily	Oral
Batch :	Started : 21/12/2006	L TERM
		Stopped : 16/10/2008

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		22/10/2008	3.30	
White blood cells		21/10/2008	2.40	
White blood cells		20/10/2008	2.30	
White blood cells		19/10/2008	2.40	
White blood cells		18/10/2008	2.10	
White blood cells		17/10/2008	2.40	
White blood cells		16/10/2008	2.20	
White blood cells		14/10/2008	3.50	
White blood cells		15/09/2008	5.00	
Neutrophils		22/10/2008	1.60	
Neutrophils		21/10/2008	0.80	
Neutrophils		20/10/2008	0.50	
Neutrophils		19/10/2008	0.90	
Neutrophils		18/10/2008	1.10	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		17/10/2008	0.70	
Neutrophils		16/10/2008	1.00	
Neutrophils		14/10/2008	1.50	
Neutrophils		15/09/2008	2.60	

Public Case Detail

Cases Count: 393

Case Number : 247707

Data Entry Date : 14/01/2009
Hospitalisation : Admitted to hospital
Onset Date : 10/10/2008
Outcome :
 Unknown

Gender : M
Weight (kg) : 0
Age :
DOB : 28/11/1991
Causality : Causality possible

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed drug induced myocarditis and cardiac complication myocarditis.	Clozaril discontinued.

Medicine details :			
CLOZARIL (Suspected)		Reason : Unspecified schizophrenia	
Tablet	275 Milligram	Daily	Oral
Batch :	Started : 25/09/2008	Stopped : 10/10/2008	

Public Case Detail

Cases Count: 393

Case Number : 247890

Data Entry Date : 21/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 09/10/1971

Unknown

Causality : Causality possible

Information: History of schizophrenia, depression and obesity. Hepatic steatosis, gastro-oesophageal reflux (medically significant) assessed as unlisted according to Core Data Sheet.

Reaction :

Preferred Term	Severity	Report Description	Treatment
Left atrial dilatation		Patient experienced impaired glucose tolerance which was presently normal. Patient also had fatty liver changes on liver function tests and gastro-oesophageal reflux and obesity.	
Blood cholesterol increased			
Gastrooesophageal reflux disease			
Glucose tolerance impaired			
Hepatic steatosis			
Liver function test abnormal			
Obesity			

Medicine details :

CLOZARIL (Suspected)	Reason : Unspecified schizophrenia
Tablet	Oral
Batch :	Started : 08/12/2001 L TERM Stopped :

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Liver function tests				The patient also had fatty liver changes on liver function tests and gastro-oesophageal reflux.
Other data				Blood cholesterol high: 6.0 mmol/l, Blood triglycerides high: 3.4
Echocardiogram		27/10/2008	Normal with leftward axis noted.	Echocardiogram: Normal left ventricular size, wall, thickness and systolic function with mild left atrial enlargement.

Public Case Detail

Cases Count: 393

Case Number : 247920

Data Entry Date : 22/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2008

Age :

DOB : 13/08/1965

Outcome :

Causality : Causality possible

Recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced a pulmonary embolism whilst being treated with Clopine.	Ceased fluvoxamine.

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	350 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
FLUVOXAMINE MALEATE (Suspected)		Reason :	
	100 Milligram	Daily	Oral
Batch :	Started :	Stopped :	
LITHIUM CARBONATE (Other drug)		Reason :	
Batch :	Started :	Stopped :	
ZUCLOPENTHIXOL DECANOATE (Other drug)		Reason :	
Batch :	Started :	Stopped :	

Public Case Detail

Cases Count: 393

Case Number : 247923

Data Entry Date : 22/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/11/2008

Age :

DOB : 11/07/1958

Outcome :

Causality : Causality possible

Not yet recovered

Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia and leucopenia.	Ceased Clopine
Leukopenia			

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	150 Milligram	Daily	Oral
Batch :	Started :	Stopped :	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells		15/10/2008	4.10	
White blood cells		12/11/2008	2.60	
White blood cells		13/11/2008	2.40	
White blood cells		15/11/2008	2.40	
White blood cells		17/11/2008	2.30	
White blood cells		19/11/2008	3.20	
White blood cells		20/11/2008	3.10	
White blood cells		21/11/2008	2.30	
White blood cells		22/11/2008	2.60	
White blood cells		24/11/2008	2.40	
White blood cells		25/11/2008	3.00	
White blood cells		26/11/2008	3.10	
Neutrophils		15/10/2008	2.40	
Neutrophils		12/11/2008	1.40	
Neutrophils		13/11/2008	1.20	
Neutrophils		15/11/2008	1.00	
Neutrophils		17/11/2008	0.90	
Neutrophils		19/11/2008	1.80	
Neutrophils		20/11/2008	2.00	
Neutrophils		21/11/2008	1.00	
Neutrophils		22/11/2008	1.20	

Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		24/11/2008	1.20	
Neutrophils		25/11/2008	1.70	
Neutrophils		26/11/2008	1.60	

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: CLOPINE, CLOZAPINE, CLOZARIL